

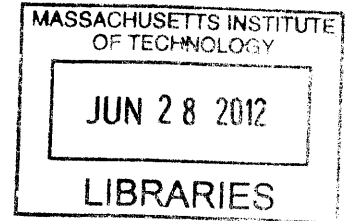
Design of a Low-cost Autoclave for Adoption in Rural Health Posts of the Developing World

by

Gregory Tao

B.S. Mechanical Engineering (2010)

Massachusetts Institute of Technology



Submitted to the Department of Mechanical Engineering
in Partial Fulfillment of the Requirements for the Degree of
Master of Science in Mechanical Engineering

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ABSTRACT

Incidence of surgical site infection is two to five times higher in developing nations as compared to developed nations. Autoclaves kill all dangerous pathogens, including heat-resistant endospores, and are an essential tool to achieving and maintaining a sterile environment, which decreases risk of infection. A low-cost, easy to use autoclave was designed to address the unique technical, behavioral, and market challenges present in rural health posts of the developing world. A thorough stakeholder analysis was performed very early in the design process to address needs for sustained user adoption as well as manufacturability and scalability. Twelve partnering clinics in Nepal trialed these autoclaves from July until December 2012. Usage statistics from this period and follow-up observations highlight important factors for successful adoption. These findings were used to improve the autoclave design in a second iteration.

Keywords: autoclave, sterility assurance level, surgical-site infection, rural health post,

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Table of Contents

1. Acknowledgements.....	6
2. Introduction.....	7
2.1. Problem Identification.....	7
2.2. Epidemiology.....	9
2.3. Specific Context: Nepal.....	10
2.4. Prior Art.....	11
2.5. Medical Device Requirements.....	14
3. Autoclave Design and Validation.....	18
3.1. Heat Source Analysis.....	19
3.1.1. Energy Required to Heat 1L of Water and Pressure Cooker.....	19
3.1.2. Heat Losses from Pressure Cooker.....	20
3.1.3. Power Requirements for Heating Source.....	24
3.1.4. Energy Required for Each Cycle.....	32
3.1.5. Fuel Costs in Nepal.....	32
3.1.6. Fuel Weight and Volume per Cycle.....	34
3.1.7. Minimum Solar Collector Size.....	35
3.1.8. Energy Source Pugh Chart.....	37
3.2. System Level Design – Stakeholder Analysis.....	38
3.2.1. Design for User.....	41
3.2.2. Design for Buyer.....	42
3.2.3. Design for Manufacturer.....	42
3.2.4. Design for Repair.....	43
3.3. Mechanical and Biological Testing.....	43
4. Field Testing.....	
4.1. Device Delivery and Evaluation.....	48
4.2. The Donor Culture.....	50
4.3. Field Interviews and Observations.....	51
4.3.1. User.....	51
4.3.2. Buyer.....	52
4.3.3. Manufacturer.....	54
4.3.4. Repair.....	54
4.4. Summary of Field Learning.....	55
5. Redesign.....	57
5.1. Second Autoclave Iteration.....	57
5.2. Future Work.....	60
6. Conclusions.....	61
6.1. Value of Early Prototyping.....	61
6.2. Supply and Demand Structure.....	63
6.3. Design with Incomplete Information.....	65
6.4. Competitions and Networking.....	66
6.5. Team Building.....	68
7. References.....	69
8. Appendix A – Sterilization Methods.....	72

Table of Figures

Figure 1 – Market Opportunity	13
Figure 2 – Microbe Population vs. Steam Temperature and Exposure Time	17
Figure 3 – Energy Required during Heating and Boiling	20
Figure 4 – Linear Approximation of Radiation Equation	22
Figure 5 – Pressure Cooker Thermal Resistance Network	24
Figure 6 – Heat Absorbed by the Pressure Cooker vs. the Time to Reach Boiling	26
Figure 7 – Surface Temperature during Heating	28
Figure 8 – Distribution of Heat Absorbed over Time to Thermal Mass and Losses	29
Figure 9 – Required Power from Fuel Sources based on Heater Efficiencies	31
Figure 10 – Cost per Cycle for Each Fuel Source	33
Figure 11 – Fuel Weight and Volume per Cycle vs. Fuel Source	34
Figure 12 – Autoclave Design – 1 st Iteration	40
Figure13 – Experimental Setup – Pressure and Temperature Measurement.....	44
Figure14 – Internal Steam Pressure and Temperature vs. Time.....	45
Figure15 – Biological Testing with 3M Attest Spore Vials	47
Figure16 – Autoclave Adoption.....	49
Figure17 – Medical Device Procurement Chain.....	53
Figure18 – Autoclave Design – 2 nd Iteration	59
Table 1 – Effectiveness of Cleaning Methods	8
Table 2 – Microbe Thermal Properties -D and Z values	15
Table 3 – Stove Power Output Required from Various Fuel Sources	30
Table 4 – Total Energy Required per Cycle from Each Fuel Sources.....	32
Table 5 – Summary of Energy Calculation for the 4L Pressure Cooker	36
Table 6 – Summary of Energy Calculation for the 23L Pressure Cooker	36
Table 7 – Pugh Chart for Energy Source Selection	37
Table 8 – Design Requirements for 1 st Iteration	39
Table 9 – Design Requirements Revised for 2 nd Iteration	57

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2 INTRODUCTION

2.1 PROBLEM IDENTIFICATION

The incidence of surgical-site infections (SSIs) ranges from 5-20% in developing world hospitals, dramatically higher than the SSI incidence of 2-3% in US and European hospitals¹. The World Health Organization (WHO) estimates that the incidence of SSI is even greater in rural, resource-constrained clinics of the developing world, nearing 30% in some settings². These infections place an acute economic burden on poor patients who must repeat or prolong their hospital stay and absorb not only the living and travel expenses but also lost income from not being able to work during their trip and stay.

The way in which reusable instruments are cleaned between invasive procedures is of particular importance to the risk of SSI. The WHO states that inadequate equipment, lack of basic infection control knowledge and implementation, and unsafe procedures elevate the risk of SSI². Studies of post-surgical infection in Tanzania conducted by Fehr et. al.³ and Erikson et. al.⁴ suggest that contaminated instruments were responsible for introducing pathogens into the deep tissue layers during surgical intervention, with a failure of their current autoclave system throughout the study cited as a root cause. These studies found that SSIs in deep tissue layers and in organ space represented 62% and 79% of observed SSIs as compared to 4% in a Bolivian study⁵ where similar environmental constraints were present but an operable autoclave was in use.

Many cleaning methods exist with varying degrees of efficacy (Table 1). Decontamination is appropriate for hospital surfaces. High-level disinfection (HLD) kills 95% of microbes but fails to kill endospores that cause tetanus and gas gangrene because the strains are particularly robust to heat and chemical exposure. Currently, HLD is the best alternative and commonly used in

rural health posts (RHPs) where sterilization equipment is unavailable. Sterilization eliminates 100% of microbes, which is required for invasive surgical instruments. It is achieved by a multitude of methods, the simplest of which is steam autoclaving.

Table 1 | Effectiveness of microbe elimination by cleaning procedure⁶.

METHOD	EFFECTIVENESS (eliminate microorganisms)	OPERATION END POINT
Cleaning (water and soap)	Up to 50-80%	Until visibly clean
Decontamination (0.5% chlorine soln.)	Kills HBV, HIV, and most microorganisms	10 minutes
High Level Disinfection (boiler)	Up to 95% (many endospores survive)	Boiling, steaming, or chemicals for 20 minutes
Sterilization (autoclave)	100%	High-pressure steam, dry heat, or chemical for recommended time

The design process presented here seeks to improve autoclave adoption by creating an autoclave that meets not only the technical specifications, but also the social and business factors that are critical to sustained adoption and scalability. Stakeholders including users, buyers, distributors, manufacturers, and repairmen were all consulted during throughout the design process to tailor the autoclave design to meet their eclectic and sometimes opposing sets of needs. Field evaluations of the autoclave were performed in Nepal to better understand important factors to autoclave adoption at the individual clinic level and potential for adoption at the system level. A team of two Nepali undergraduate students and two graduate students with engineering and business expertise, including myself, worked collaboratively towards these goals since January 2011.

2.2 EPIDEMIOLOGY

Both the *Clostridium* and *Bacillus* genera of bacteria are capable of producing endospores that readily withstand extended exposure to boiling water^{7,8}. The most dangerous and prevalent species are *C. difficile*⁸⁻¹⁰, which leads to violent diarrhea, and *C. tetani*, which leads to tetanus⁷. Despite its low prevalence, *C. difficile* causes severe diarrhea with a high mortality rate of 6%–30%¹⁰ and represents a significant clinical hazard as its resistance evolves in a similar fashion to other super bugs such as methicillin-resistant *Staphylococcus aureus*, better known as a “Staph infection.” *C. tetani* acts via release of an extremely potent neurotoxin that results in uncontrollable, excruciating muscle spasms but also maintains consciousness in the victim.

Neonatal and maternal tetanus, caused by the endospore *C. tetani*, remains a significant global health burden in 48 developing nations, while tetanus in the developed world has been reduced to a medical curiosity. Population-wide vaccination with a tetanus toxoid vaccine has proven an effective intervention against tetanus in nations around the world and is primarily responsible for lowering the number of tetanus-induced deaths in the developing world from >1million in 1980 to around 250,000 today^{7,11}. However, lack of vaccine access and cultural resistance are especially high in rural populations and keep these populations at significantly elevated risk of neonatal and maternal tetanus, which still account for 5-7% worldwide neonatal mortality^{12,13}. Multivariate analyses of risk factors for neonatal and maternal tetanus include unclean hands and instruments¹⁴⁻²⁰.

Poor adherence to correct boiling protocols - incomplete immersion of tools, failure to remove residual debris, and insufficient boiling time – foster survival of non-sporulating pathogens with intermediate heat resistance. These quality control failures increase patients’ risk of SSI and were observed in all RHPs and rural hospitals visited by the team. The large number

of RHPs worldwide amplifies the scale of the problem. According to the WHO, there are over 3,500 government-run RHPs in Nepal²¹ and over 30,000²² in India. We estimate that there are 150,000 RHPs worldwide. Based on published infection rates and patient volumes¹ (20% and roughly 2 surgical patients per day), we conservatively estimate that RHPs alone are responsible for over 15 million SSIs annually.

2.3 SPECIFIC CONTEXT: NEPAL

The risk of SSI in Nepal, the site of field trials, is 7.3% in urban hospitals²³ and undoubtedly higher in RHPs where infection control is much worse and SSI incidence is poorly documented. Nepal was selected to focus the research due to the high risk of SSI as well as contextual knowledge provided by Nepalese students at MIT with connections to the healthcare industry. Nepali hospitals perform major surgical procedures and are equipped with steam autoclaves and knowledgeable personnel to operate them. The Nepali doctors are trained in these hospitals and are aware of the importance of sterilization. However, they rarely visit RHPs, and the vast majority of nurses left in charge have never been exposed to an autoclave. RHP staff perform minor surgical procedures – deliveries, wound cleaning, and suturing – but, due to a lack of financial resources and trained staff, fail to use autoclaves, elevating the risk of SSI in their patients.

The Nepali government distributed pressure cookers for use as autoclaves in the early 1990s, but the pressure cookers were removed during the civil war from 1996 to 2006²⁴ because of their use as bomb-making material. New infection control workshops train RHP staff on the importance of hand washing and autoclaving among other measures. During the team's first trip to Nepal in the summer of 2011, the team visited twenty different pre-screened healthcare

facilities including many RHPs. The RHP staff that we interviewed who had attended these workshops had a poor understanding of what an autoclave was and certainly did not use them in their RHPs. Instead, RHP staff preferred and used boilers because they required less time and attention.

2.4 PRIOR ART

The first autoclave, designed by Chamberland in 1879²⁵, looked strikingly similar to modern day pressure cookers. Since then, the autoclave has become an essential tool for hospitals, with vendors offering autoclaves that vary widely in size and sophistication. Autoclaves designed for developed world markets have many features that maximize safety and automation and cost anywhere from \$3,000 to >\$100,000 USD depending on size and automation²⁶. Less expensive autoclave designs popular in developing world markets lack progress monitoring features, focus more on robustness, and cost anywhere from \$250 to \$5,000 USD depending on size²⁷.

Small autoclaves designed for small healthcare facilities of the developing world come in a variety of sizes from 4L to 60L²⁷ and are robust. Unfortunately, most of the small autoclave designs require electricity, which is often unavailable in RHPs. Additionally, these autoclaves are often prohibitively expensive compared to electric boilers, which are only \$10-20 USD. Even when an autoclave is present in a health post, appropriate use poses a significant challenge, as the process is not intuitive. Training is limited or non-existent, paper instructions are not included for the multi-step autoclaving process. Thus, unskilled and often illiterate nurses' assistants fail to operate the autoclave correctly, which decreases the quality of sterilization and increases the risk of SSI.

In lieu of an autoclave, the low cost of consumables (water and heat) and ease of use make boiling the most widespread disinfection measure in Nepali RHPs. All the RHPs the team visited in Nepal boiled their instruments. Bathing surgical equipment in a chemical solution (e.g. chlorhexidine or glutaraldehyde solutions) is sometimes used to disinfect latex examination gloves and is used by mobile surgical camps due to its portability and electricity independence. These measures, however, are still clinically inferior and elevate the risk of SSI. The prevalence of these practices was observed in all partnering RHPs during the authors' first trip to Nepal in the summer of 2011.

Clinicians and researchers from around the world have developed many different autoclaves to address poor autoclave usage by focusing on either manufacturing or energy source. Oyawale and Olaoye²⁸ developed a low-cost autoclave in Nigeria from locally available materials and manufacturing skills of the researchers. While the product is well designed for low-cost and local manufacturability, it operates on electricity where many developing world environments have frequent power outages, and there are significant safety concerns around quality control of a locally welded pressure vessel. Other groups are focusing on ways to heat the pressure vessel²⁹ or retrofit current autoclaves to make them portable for surgical camps.³⁰ However, there remains a significant opportunity to improve appropriate autoclave use by creating an autoclave that is low cost enough to fit a RHP's budget and simple enough for untrained nurses' assistants to learn and use (Fig. 1).

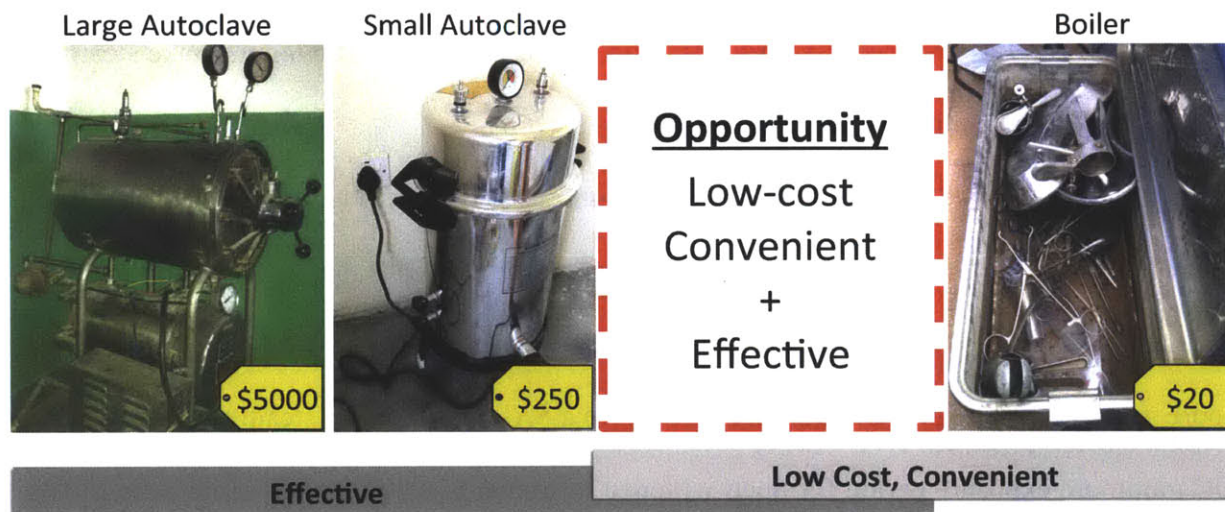


Figure 1 | There is a gap in the sterilization market for an autoclave that is effective at killing all microbes, low-cost to facilitate RHP access, and convenient to drive sustained adoption. Current autoclaves in developing world markets remain too expensive for RHPs and are much less convenient than boiling, taking over an hour to operate. Boiling, the prevailing substitute is low-cost and convenient, but fails to effectively eliminate all dangerous pathogens. Convenience – ease of use, monitoring time, and monitoring effort – is a significant driving factor for product adoption, even for developing world technologies.

2.5 MEDICAL DEVICE REQUIREMENTS

Sterilization destroys all microorganisms on a surface to prevent disease transmission via that object. Many different methods can be employed to sterilize medical instruments including steam or dry heat, chemicals, and radiation. A thorough analysis of these sterilization methods is presented in Appendix A. High temperature steam heating by boiling water at high pressure can be achieved using a household pressure cooker, ubiquitous even in remote regions of the developing world. Ease of access, simplicity of operation, and non-exotic inputs make steam autoclaving a viable choice for the developing world setting.

Sterility is quantified as the probability of one microorganism surviving on an object, also known as the sterility assurance level (SAL). The CDC recommends that invasive surgical instruments achieve a sterility assurance level (SAL) of 10^{-6} - conditions where the probability of a spore surviving is one in one million³¹. To achieve a SAL of 10^{-6} using steam sterilization, the CDC minimum exposure period for linen-wrapped instruments is 30 minutes while maintaining 121°C and 203kPa absolute pressure^{31,32}.

The steam exposure time and temperature required to achieve a specific SAL are different for each microbe and determined by the microbe's thermal resistance properties (D,Z) and the initial number of microbes on a sample (P_0), which is also known as the bioburden. For a given steam temperature and pressure, each microbe has a specific decimal reduction time (D) - the time required for a 1-log reduction in that microbe's population. The D-value is the characteristic time, similar to a time constant, for microbe population reduction and has units of

$\left[\frac{s}{1-\log \text{reduction}} \right]$, where the 1-log reduction is effectively unit-less. Given the microbe type and exposure temperature, the estimated microbe population, P, becomes a function of exposure time, t, and the initial microbe population, P_0 .

$$P(t, P_0) = P_0 \cdot 10^{-t/D} \quad (1)$$

Population, P, and initial number of microbes, P₀, are both measured in colony-forming units (CFUs), which are essentially the number of viable microbes that remain. In the range P>1, P represents the estimated number of surviving microbes, which is a true population. In the range P<1, P represents the probability of survival for the last remaining microbe, which is more of a theoretical population. This microbe survival probability is the same as the sterility assurance level or SAL.

A microbe's D-value, or population reduction time scale, is heavily dependent on the exposure temperature. The Z-value is the temperature change required to result in a 1-log reduction in D-value, or a ten times slower kill rate.

$$D(T) = D_{121C} \cdot 10^{(121C-T)/Z} \quad (2)$$

D-values are calculated relative to an established standard for each microbe. 121°C is used here because it is the standard autoclave operating temperature.

D-values, the effective kill rate, are empirically derived at much lower temperatures, around 65°C, for heat-sensitive bacteria and viruses³³ (Table 2).

Table 2 | The decimal reduction time required to reduce a microbes population by 90% or 1-log at 70°C (D_{70C}) is shown below for a variety of p microbes. Greater D values represent greater heat resistance. *G. Stearothermophilus* is a non-pathogenic endospore used for autoclave validation that has thermal resistance properties that are similar to those of the heat-resistant pathogenic endospores, *C. tetani* and *C. difficile*, mentioned in section 2.2.

**Extrapolated from D_{121C} and Z for *G. Stearothermophilus*.

Microbe	Microbe Classification	$\left[\frac{D_{70C}}{s} \right]$ [1-log reduction]	$\left[\frac{Z}{^{\circ}C} \right]$ [1-log reduction in D]
<i>Geobacillus Stearothermophilus</i>	Endospore	3.6x10 ⁸ **	8.0
<i>Enterococcus Faecium</i>	Bacteria	105.5	9.5
<i>Escherichia Coli (E.coli)</i>	Bacteria	0.9	6.0
<i>Salmonella Senftenberg</i>	Bacteria	0.2	5.8

The CDC employs an “overkill” approach where worst-case conditions are assumed - 10^6 of a highly heat-resistant spore forming bacteria, such as *G. Stearothermophilus* ($D_{121C}=2.5\text{min}$, $Z=8^{\circ}\text{C}$). Under these conditions it will take 15 minutes to eliminate all but one spore (15min/2.5 min per log reduction = 6-log reduction) and another 15 minutes to achieve a SAL of 10^{-6} .

The estimated population is ultimately a function of exposure time (t), exposure temperature (T), and the microbe’s thermal properties (D_{121C} , Z). The combination of equations 1 and 2 results in a holistic expression for microbe elimination.

$$P(t, T, Z, D_{121C}) = P_0 \cdot 10^{\left[-\frac{t}{D_{121C} \cdot 10^{(121C-T)/Z}} \right]} \quad (3)$$

This aggregate equation is displayed graphically (Fig. 2) for *G. Stearothermophilus* with a initial bioburden, $P_0 = 10^6$. Exposure time has an exponential influence on the population reduction, $-\log(P) \propto t$. Exposure temperature is even more powerful with a double exponential influence on population reduction, $-\log(\log(P)) \propto T$.

As the steam temperature decreases, the exposure time required to reach a SAL of 10^{-6} increases via a double exponential. Iterative boiling over multiple days is the only way to kill endospores and achieve the SAL of 10^{-6} with steam temperature of 100°C . This helps explain the inferior cleaning capabilities of simple boiling at atmospheric pressure, and the need for a pressure vessel that can achieve higher steam temperatures.

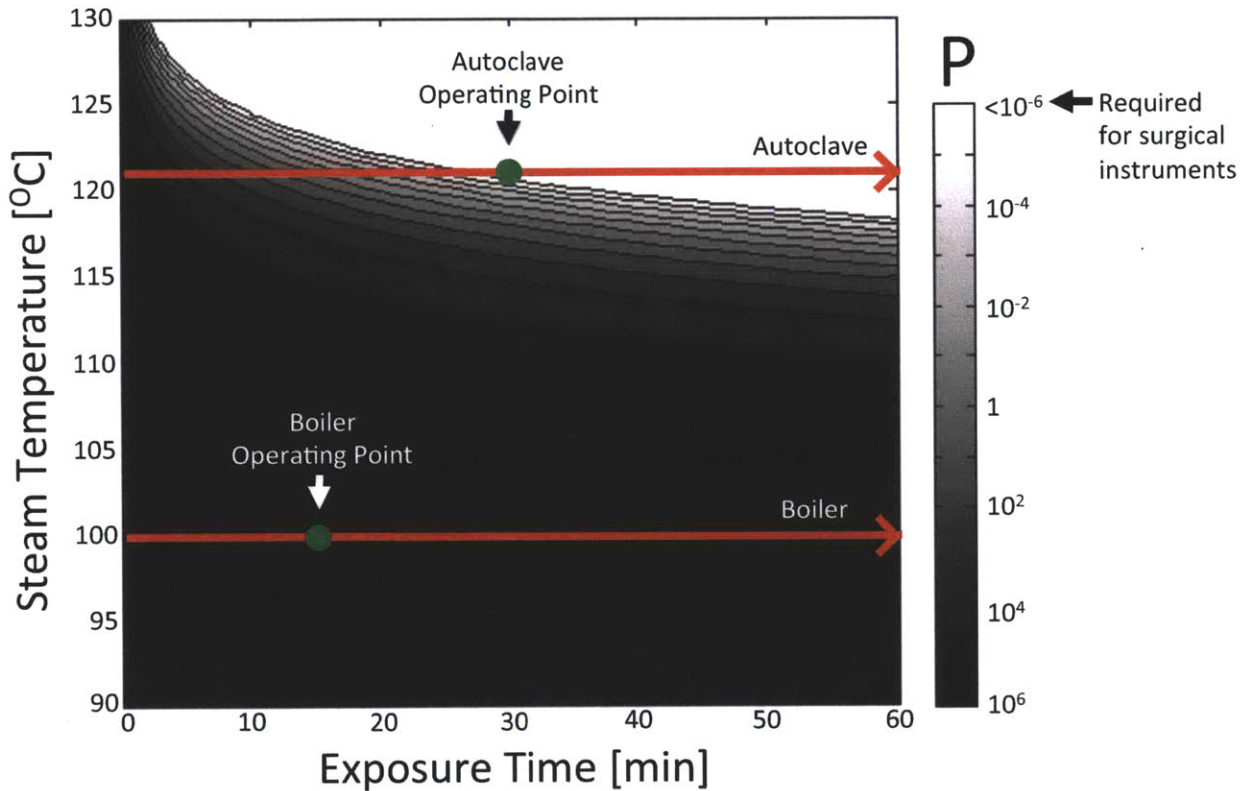


Figure 2 | Assuming an initial population of 10^6 *G. Stearothermophilus* endospores, the effective endospore population (P) is reduced at varying rates depending on steam temperature. P represents the estimated population of endospores for $P > 1$ and the probability of one surviving endospore, also known as SAL, for $P < 1$. A SAL of 10^{-6} , represented by the white region, is required for surgical instruments. The green dots are the typical clinical operating times for boilers and autoclaves. The endospore population after boiling is virtually the same as the initial population of 10^6 , $P_{100C,15min} = 5.97 \times 10^5$. The endospore population is effectively eliminated that result in very different microbe populations: versus $P_{121C,30min} = 1 \times 10^{-6}$.

3 AUTOCLAVE DESIGN AND VALIDATION

3.1 HEAT SOURCE ANALYSIS

The heating source was a central determinate of the design after steam autoclaving was chosen as the method of autoclaving. Thus, this fundamental design decision warranted robust analysis of the energy sources available. The most common energy sources in Nepal are liquid propane gas (LPG) similar to propane canister for a grill, electricity, wood, and kerosene. Electricity is unreliable in urban environments but is especially unreliable in rural settings, the location of RHPs, where power outages can knock out electricity for the majority of the day. There are also handful of donated solar collectors throughout Nepal, but are rarely used due to inconvenience and lack of sun.

The following energy analysis was performed in order to select an energy source that would drive the rest of the design. Calculations are performed for a 4-quart³⁴ and a 23-quart³⁵ pressure cookers. These models represent the extremes of the pressure cookers size spectrum.

Experimental Steam outflow rate

The pressure cooker and water inside were massed before and after the autoclave cycle. The autoclave was closed throughout the massing process to minimize evaporation losses that would artificially increase the calculated mass flow rate.

$m_{\text{initial}} = 2,423 \text{ g}$ (including 4L pressure cooker)

$m_{\text{final}} = 2,273 \text{ g}$

$t_{\text{boil}} = 30 \text{ min}$

$$\frac{dm}{dt} = \frac{m_{\text{initial}} - m_{\text{final}}}{t_{\text{boil}}} = 5\text{g/min} \quad (4)$$

3.1.1 Energy Required to Heat the Thermal Mass

The energy required to heat a certain mass of a substance (ΔU) is a function of the material's specific heat capacity (c_p), the change in temperature (ΔT).

$$\Delta U = mc_p\Delta T \quad (5)$$

The energy required to boil a certain mass of liquid (ΔH_{vap}) is determined by the material's specific enthalpy of vaporization (ΔH_{vap}^o).

$$\Delta H_{vap} = m\Delta H_{vap}^o \quad (6)$$

Water: $C_p = 4.1855 \frac{J}{g \cdot K}$, $\Delta H_{vap}^o = 2260 \frac{J}{g}$

Aluminum: $C_p = 0.902 \frac{J}{g \cdot K}$

Assumptions:

*1L of water is typically required for safe autoclaving to ensure the device does not run out of water if it is left unattended.

*Roughly 150mL of water boils off over the thirty minute boiling period that is required to achieve sterilization. This total steam loss is based on the steam loss rate of 5g/min from eqn. 4.

*The pot weights were approximately 2kg (4L cooker) and 5 kg (23L cooker).

$$\Delta U_{Al,small} = (2\text{kg}) \cdot \left(0.902 \frac{J}{g \cdot K}\right) \cdot (100^\circ C - 25^\circ C) = \mathbf{135kJ}$$

$$\Delta U_{Al,large} = (5\text{kg}) \cdot \left(0.902 \frac{J}{g \cdot K}\right) \cdot (100^\circ C - 25^\circ C) = \mathbf{338kJ}$$

$$\Delta U_{water} = \left(1\text{L water} \cdot \frac{1000g}{1L}\right) \cdot \left(4.1855 \frac{J}{g \cdot K}\right) \cdot (100^\circ C - 25^\circ C) = \mathbf{314kJ}$$

$$\Delta H_{vap,water} = \left(150\text{mL water} \cdot \frac{1g}{1mL}\right) \cdot \left(2260 \frac{J}{g}\right) = \mathbf{339kJ}$$

Energy Requirements are graphed in Fig. 3.

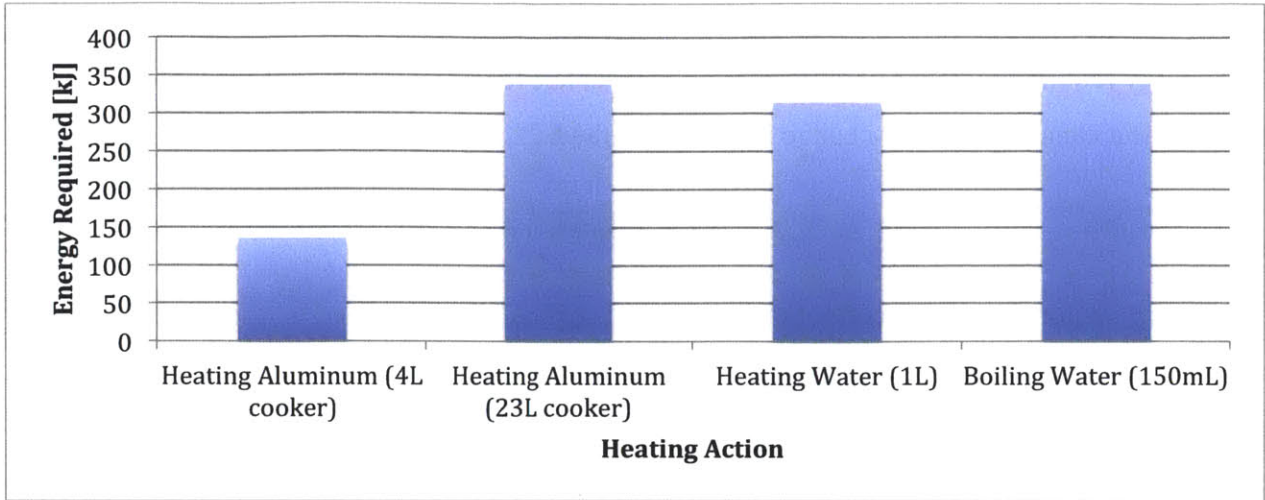


Figure 3 | The energy required to heat the thermal mass and boil off 150mL of steam are shown above. The energy required to heat Heating and boiling the water accounts for the majority of the required energy at ~650KJ. Heating the body of the small cooker takes less than half the energy required to heat the larger cooker.

3.1.2 Estimated Heat Losses from Pressure Cooker

Steam Outflow Heat Loss

As steam exits the pressure vessel, it must be continuously replaced with new steam in order to maintain a constant internal pressure.

$$Q_{\text{steam loss}} = \frac{dm}{dt} \Delta H_{\text{vap}} = \left(\frac{5g}{\text{min}} \cdot \frac{\text{min}}{60s} \right) \cdot 2260 \frac{\text{J}}{\text{g}} = 188\text{W} \quad (7)$$

Lumped Thermal Capacitance (LTC) Model

The LTC model is assumed to simplify the calculations for heat losses from radiation and convection. Both equations result require a known surface temperature, and the LTC model assumes that the thermal mass is isothermal, thereby making the surface temperature uniform as well. This approximation assumes that the heat flows much more easily inside the object than heat flows off the surface of the object. The validity of the LTC model is tested by calculation of the Biot number (13). The LTC model states that the thermal mass is roughly isothermal and the surface temperature is uniform, which would be the same as the internal steam temperature (121C). Calculations are also performed for 150C, which would yield a more conservative estimate of the power losses. The average heat loss values from these limits are calculated, which is reasonable first-order approximation of power losses.

Convection Heat Loss

$$Q_{\text{convection}, T_s=120C} = h_c A \Delta T \quad (8)$$

$$h_c = 10 \frac{W}{m^2 K}$$

*assume only the circumference and top surfaces are losing heat to convection

$$Q_{\text{convection}, T_s=120C} = h_c A \Delta T = \left(10 \frac{W}{m^2 K}\right) \cdot (0.191 m^2) \cdot (393K - 298K) = 181.9W$$

$$Q_{\text{convection}, T_s=150C} = h_c A \Delta T = \left(10 \frac{W}{m^2 K}\right) \cdot (0.191 m^2) \cdot (423K - 298K) = 239.4W$$

$$Q_{\text{convection}, \text{small}} \approx \mathbf{200W}$$

$$Q_{\text{convection}, \text{large}} \approx \mathbf{450W}$$

Radiation Heat Loss

The heat transfer from radiation is described below both in the Stefan-Boltzmann's Law.

$$Q_{\text{radiation}} = \epsilon \sigma A (T_s^4 - T_{\text{amb}}^4) \quad (9)$$

$\epsilon = 0.25$ for a shiny pot surface³⁵

$$\sigma = 5.67 \cdot 10^{-8} \frac{W}{m^2 K^4}$$

$$A_{\text{small}} = A_{\text{circumference}} + 2A_{\text{end}} = (15\text{cm} \cdot \pi \cdot 23\text{cm}) + 2 \cdot \pi (11.5\text{cm})^2 = 0.191 m^2$$

$$A_{\text{large}} = A_{\text{circumference}} + 2A_{\text{end}} = (32\text{cm} \cdot \pi \cdot 32\text{cm}) + 2 \cdot \pi (16\text{cm})^2 = 0.483 m^2$$

$$T_{\text{amb}} = 298K$$

$$T_{s, \text{final}} = 393K \text{ or } 120C$$

$$Q_{\text{radiation}, T_s=120C} = (0.25) \left(5.67 \cdot 10^{-8} \frac{W}{m^2 K^4}\right) (0.191 m^2) ((393K)^4 - (298K)^4) = 43.3W$$

$$Q_{\text{radiation}, T_s=150C} = 65.5W$$

$$Q_{\text{radiation}, \text{small}} \approx \mathbf{55W}$$

$$Q_{\text{radiation}, T_s=120C} = 109.5W$$

$$Q_{\text{radiation}, T_s=150C} = 165.6W$$

$$Q_{\text{radiation}, \text{large}} \approx \mathbf{130W}$$

The radiation heat transfer equation (7) can be linearized about T_s where the ambient and surface temperatures are close.

$$Q_{\text{radiation,linear}} = \epsilon\sigma A T_{\text{ave}}^3 (T_s - T_{\text{amb}}) = h_r A (T_s - T_{\text{amb}}) \quad (10)$$

where

$$T_{\text{ave}} = \frac{T_s + T_{\text{amb}}}{2} \quad (11)$$

$$h_r = \epsilon\sigma T_{\text{ave}}^3 \quad (12)$$

$$T_{\text{ave}} = \frac{398\text{K} - 298\text{K}}{2} = 348\text{K}$$

$$h_r = 2.39 \frac{\text{W}}{\text{m}^2\text{K}}$$

The fourth order radiation equation (9) is compared to the linearized approximation (10) within the temperature range spanning the ambient temperature, 25°C , and the approximate surface temperature, 121°C (Fig. 4).

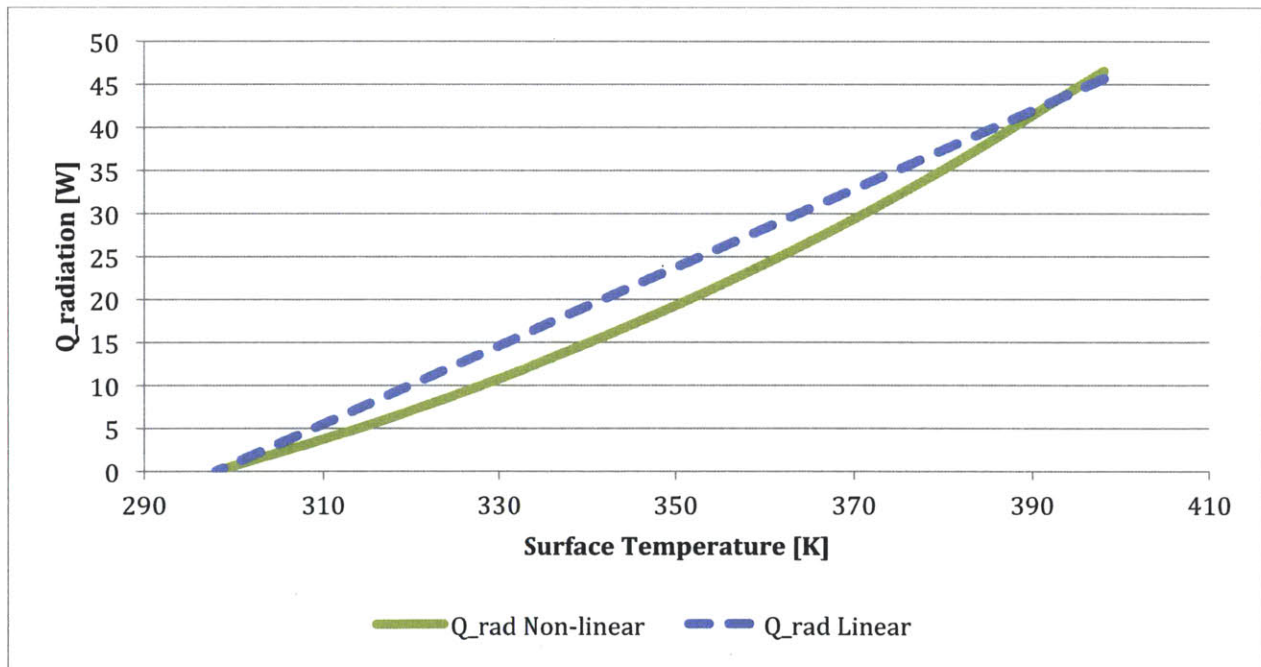


Figure 4 | The actual and linearized radiation heat transfers are shown for the small pressure cooker. The linear approximation (blue) tracks the actual fourth order radiation equation (green) well within the relevant surface temperature range, 25°C to 125°C . The maximum deviation in this range is 4.5W .

The lumped thermal capacitance model validity is quantified via the Biot number (B_i) - a ratio of the internal thermal resistance to the surface's thermal resistance. $B_i < 0.1$ is the standard for accepting the lumped capacitance model³⁷. A detailed thermal resistance network is shown in Fig. 5.

$$B_i = \frac{R_{\text{internal}}}{R_{\text{surface}}} \quad (13)$$

$$R_{\text{surface}} = \frac{1}{\frac{1}{R_{\text{conv}}} + \frac{1}{R_{\text{rad}}}} = \frac{1}{h_{\text{conv}} + h_{\text{rad}}} \quad (14)$$

$$R_{\text{convection/radiation}} = \frac{1}{h} \quad (15)$$

$$R_{\text{surface}} = \frac{1}{10 \frac{W}{m^2K} + 2.4 \frac{W}{m^2K}} = 0.08 \frac{m^2K}{W}$$

$$R_{\text{internal}} = R_{Al} + R_{Al,water} + R_{water} \quad (16)$$

$$R_{\text{conduction}} = \frac{L_c}{k} \quad (17)$$

$$k_{\text{Aluminum}} \approx 250 \frac{W}{mK}$$

$$L_c \approx 0.005m \text{ (pressure cooker thickness is characteristic length, } \sim 0.5\text{cm)}$$

$$R_{Al} = \frac{0.005m}{250 \frac{W}{mK}} = 2.0 \times 10^{-5} \frac{m^2K}{W}$$

$$h_{\text{conv,water}} \approx 100 \frac{W}{m^2K}$$

$$R_{Al,water} = \frac{1}{h_{\text{conv}}} = \frac{1}{100 \frac{W}{m^2K}} = 0.01 \frac{m^2K}{W}$$

$$k_{\text{water}} \approx 0.5 \frac{W}{mK}$$

$$L_c \approx 0.01m \text{ (water height in pressure cooker is characteristic length, } \sim 1\text{cm)}$$

$$R_{\text{cond,water}} = \frac{0.01m}{0.5 \frac{W}{mK}} = 0.02 \frac{m^2K}{W}$$

$$R_{\text{internal}} = 2.0 \times 10^{-5} \frac{m^2K}{W} + 0.01 \frac{m^2K}{W} + 0.02 \frac{m^2K}{W} \approx 0.03 \frac{m^2K}{W}$$

$$B_i = \frac{0.03 \frac{m^2K}{W}}{0.08 \frac{m^2K}{W}} = 0.38$$

While the B_i number, 0.38, is not less than 0.1, but the internal resistance is still lower than the external resistance. While the water may heat more slowly, the aluminum surface will be very close to the same temperature. Thus, the lumped thermal capacitance model is reasonable for

this first order estimation of thermal effects. This approximation simplifies the calculations by assuming a uniform surface temperature.

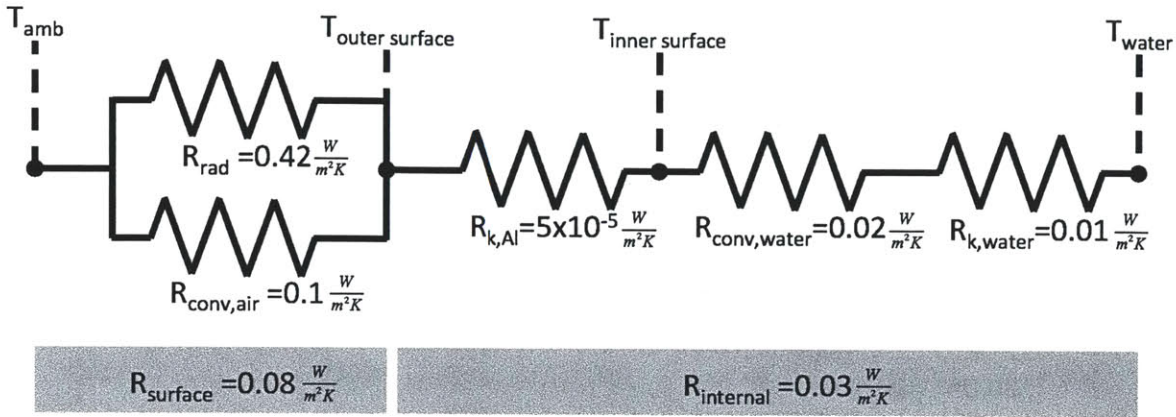


Figure 5 | The thermal resistance diagram above shows the individual and net of resistances for the internal and surface heat transfers. These values were used to calculate the Biot number and calculated the validity of the assumed lumped thermal capacitance model.

3.1.3 Estimated Power Requirements for Heating Source

The power distribution is distinctly different in two stages: the heating stage and the boiling stage. During the heating stage, $Q_{absorbed}$ goes to heating the thermal mass of the cooker and water initially. As the cooker heats up, more and more of that power is lost due to radiation and convection off the pressure cooker's surface. Once boiling begins, the pressure cooker's thermal mass remains constant and the heat losses are also constant. The power once used to heat the thermal mass is now used to produce a continuous steam outflow.

Power Required during Heating

The following equations describe the heating stage before boiling occurs. The heat absorbed by the bottom of the pressure cooker is assumed to be constant since the heating sources, such as a gas or electric stove, operate at a constant power output. A power balance shows that the heat absorbed by the bottom of the pressure cooker goes into both heating the thermal mass and losses.

$$Q_{absorbed} = \frac{dU}{dt} + P_{losses} \quad (18)$$

$$P_{losses}(T_s) = Q_{radiation} + Q_{convection} \quad (19)$$

$$\frac{dU}{dt} = C_p \frac{dT_s}{dt} \quad (20)$$

Combining equations 8,10, and 18-20 yields the following first order differential equation for surface temperature.

$$\begin{aligned}
 C_p \frac{dT_s}{dt} &= Q_{absorbed} - (Q_{radiation} + Q_{convection}) \\
 C_p \frac{dT_s}{dt} &= Q_{absorbed} - A(h_r + h_c)(T_s - T_{amb}) \\
 \frac{dT_s}{dt} + \frac{1}{c_p} A(h_r + h_c)T_s &= \frac{1}{c_p} (Q_{absorbed} + A[h_r + h_c]T_{amb})
 \end{aligned} \tag{21}$$

Using the integrating factor

$$\begin{aligned}
 \frac{dT_s}{dt} + BT_s &= C \rightarrow T_s(t) = c_1 e^{-Bt} + \frac{C}{B} \\
 B &= \frac{1}{c_p} A(h_r + h_c), \quad C = \frac{1}{c_p} (Q_{supply} + A[h_r + h_c]T_{amb}) \\
 T_s(t) &= c_1 e^{-\frac{(h_r+h_c)A}{C_p}t} + \frac{Q_{absorbed}}{(h_r+h_c)A} + T_{amb}
 \end{aligned} \tag{22}$$

from the initial boundary condition: $t=0, T_s = T_{amb}$

$$c_1 = -\frac{Q_{absorbed}}{(h_r+h_c)A} \tag{23}$$

$$T_s(t) = \frac{Q_{absorbed}}{(h_r+h_c)A} \left[1 - e^{-\frac{(h_r+h_c)A}{C_p}t} \right] + T_{amb} \tag{24}$$

solving for $Q_{absorbed}$

$$Q_{absorbed}(t, T_s) = \frac{A(h_r+h_c)}{\left[1 - e^{-\frac{(h_r+h_c)A}{C_p}t} \right]} (T_s(t) - T_{amb}) \tag{25}$$

Given the initial and final surface temperatures (25°C and 121°C , respectively), $Q_{absorbed}$ becomes a function of the system properties – h_c , h_r , and A – and the heating time required to achieve boiling (Fig. 6).

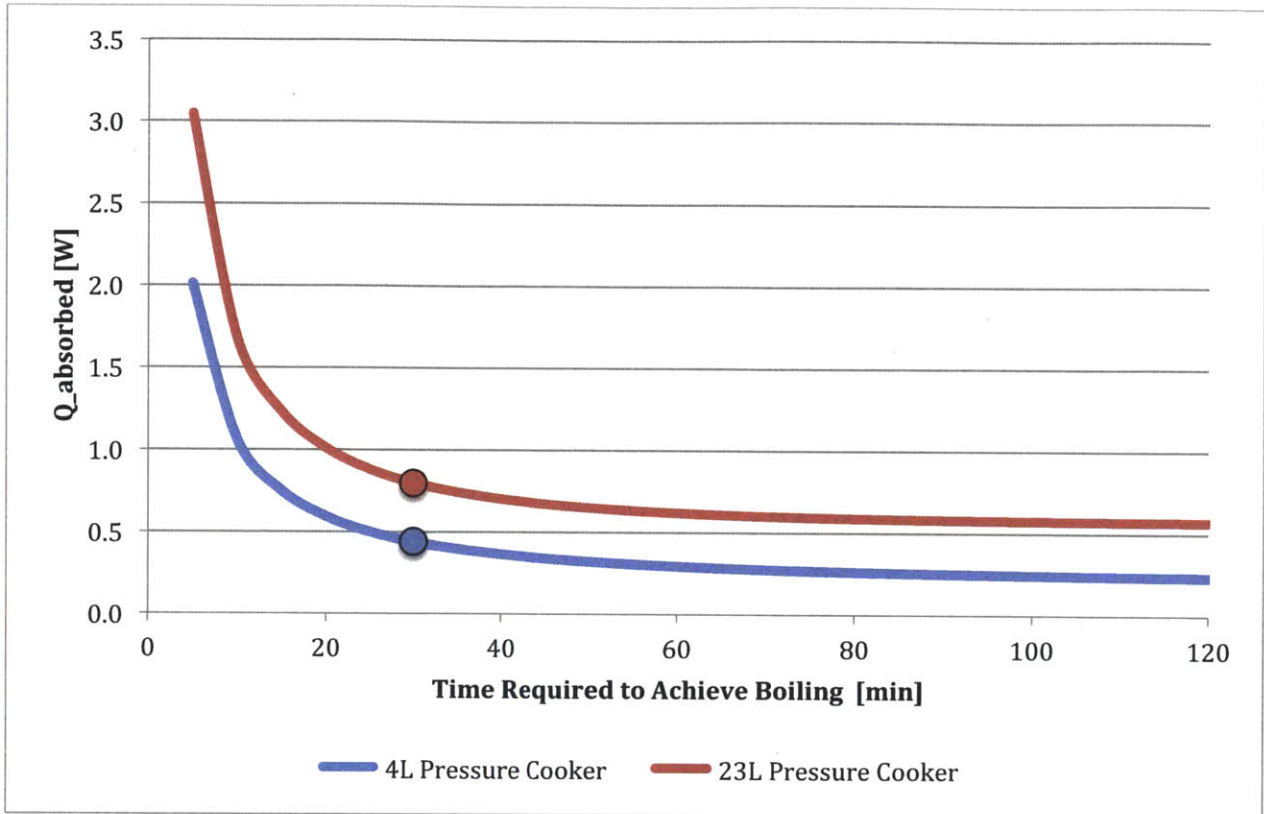


Figure 6 | The heat that must be absorbed by the bottom of the pressure cooker is determined by the heating time to achieve boiling (Eqn 25). The heating time to achieve boiling for all future calculations is 30 minutes, shown by dots. The power required increases exponentially as the time to achieve boiling becomes shorter and shorter. At very long heating times, the Q_{absorbed} asymptotically approaches 225W and 568W for the small and large pressure cookers, respectively.

Sustained high values of Q_{absorbed} would result in unreasonably high steam outflows that would likely result in a loss of the entire volume of water and damaging of the pressure vessel. Values of Q_{absorbed} close to the asymptotic limit result in really slow steam losses. Many pressure cookers have a lockout – a small stopper that “pops up” when pressure is reached - that leaks initially when pressure build up is very slow and only pops up and close the port when the steam outflow is high enough (~1g/min). This is typically not a problem where Q_{absorbed} is significantly greater than the minimum. However, where Q_{absorbed} is close to the minimum, the lockout port will continue to bleed steam and prevent the pressure cooker from pressurizing. This result would stall the heating at 100°C, and prevent the elevation of the boiling point to 121°C.

Power Required during Boiling

$$P_{\text{losses}}(T_s) = Q_{\text{radiation}} + Q_{\text{convection}} + Q_{\text{steam loss}} \quad (28)$$

Thermal losses from radiation and convection are constant because the surface temperature is at steady state. Thermal losses from steam outflow are also constant because the mass outflow is constant too.

Given the previous calculations for the small (4L) pressure cooker:

$$Q_{\text{convection,small}} \approx 200W$$

$$Q_{\text{radiation,small}} \approx 55W$$

$$Q_{\text{steam loss}} \approx 190W$$

$$P_{\text{losses, 4L cooker}} = 445W \text{ (small)}$$

Given the previous calculations for the large (23L) pressure cooker:

$$Q_{\text{convection,large}} \approx 450W$$

$$Q_{\text{radiation,large}} \approx 130W$$

$$Q_{\text{steam loss}} \approx 190W$$

$$P_{\text{losses, 23L cooker}} = 770W \text{ (large)}$$

Power Distribution of Q_{absorbed} over time

The power distribution during the heating phase is divided up between heating the thermal mass and radiation and convection losses. All of these values are a function of the surface temperature. A fixed value of Q_{absorbed} must be determined to make the surface temperature a function of only time (24). Q_{absorbed} can be determined from a given time to achieve boiling (Fig. 6), which establishes a second boundary condition.

A reasonable time to achieve boiling is one that is not so short as to require a Q_{absorbed} that is unattainable but also a time not so long as to make operation take forever and significantly inconvenience the autoclave operator. This range is approximately between 10 minutes to 30 minutes. A 30 minute heating time yields the most conservative power while still being a reasonable wait time for the autoclave operator.

The Q_{absorbed} calculated (25) for this 30 minute heating time are 442W and 801W for the small (4L) and large(23L) pressure cookers, respectively. The surface temperature profile for the small pressure cooker was calculated using $Q_{\text{absorbed}} = 442W$ (Fig. 7).

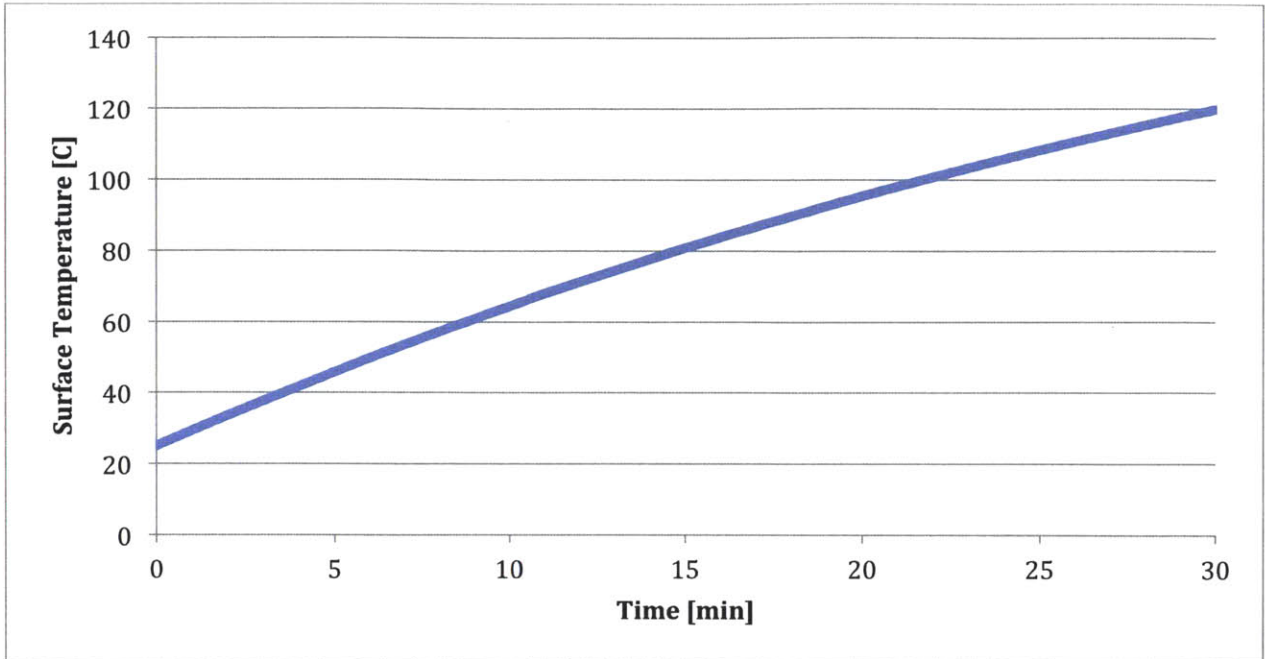


Figure 7 | The surface temperature profile is shown for the calculated Q_{absorbed} (442W and 801W) and is the same for both pressure cooker sizes. The surface temperature does indeed reach 121C at 30 minutes, which matches the boundary conditions used to determine the Q_{absorbed} value for this 30 minute heating time.

The components of power loss throughout the cycle are graphed over the course of the autoclave cycle (Fig. 8). Much more heat is lost in the larger cooker from convection and radiation due to its larger surface area. The heat loss from steam is calculated as the difference between the Q_{absorbed} also approximately the same for both systems (216W for 4L and 232W for 23L) because excess heat is dissipated through steam exiting the system. These modeled values of power lost to steam outflow are very similar to the empirically value, 190W (7). These power values correspond to steam outflows of 5.7g/min and 6.2g/min, respectively, which are very close to the 5g/min empirical value. The guiding principle is that more heat delivered causes a faster steam mass flow out of the pressure cooker.

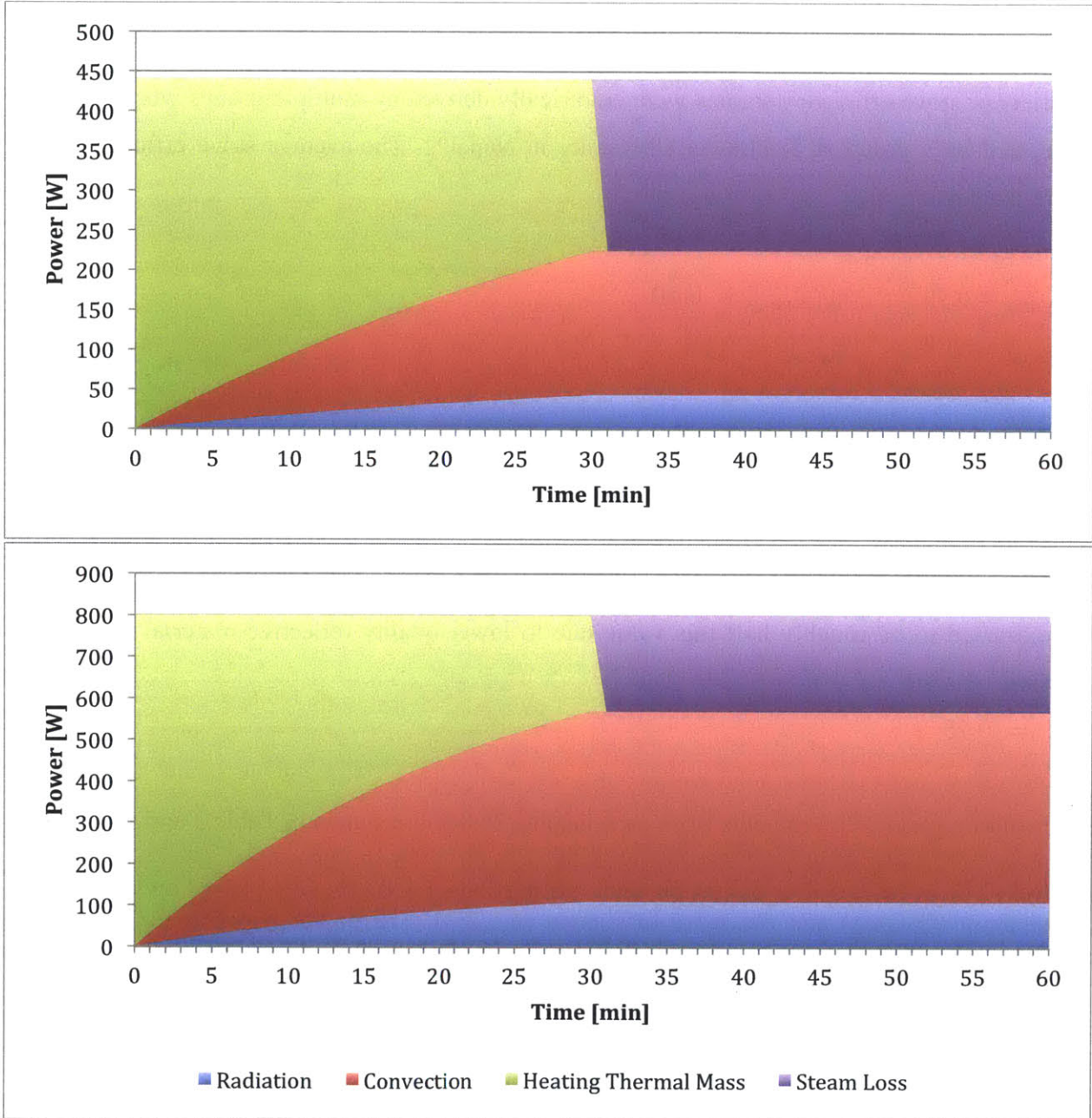


Figure 8 | The power absorbed by the bottom of the pressure cooker is split into various components: losses due to conduction and radiation, heating the thermal mass before boiling, and steam generation during boiling. The relative distribution of these heat transfers is shown for the 4L pressure cooker (top) and the 23L pressure cooker (bottom). The system stops heating up abruptly once steam starts to exit the pressure cooker. Once steam begins to exit, all extra power is expended as lost steam. The volume of the heating system component (green) is exactly the energy required to heat the pressure cooker’s aluminum body and the water inside.

Heater Efficiencies and Power Required from Various Sources

$$Q_{absorbed} = \eta_{source} Q_{source} \quad (29)$$

A variety of stove efficiency studies were empirically derived by multiple groups worldwide and aggregated by a group at Tribhuvan University in Nepal³⁸. The average stove efficiencies are reported below.

$$\eta_{electricity} = 0.70$$

$$\eta_{propane} = 0.50, \quad \eta_{kerosene} = 0.40$$

$$\eta_{charcoal} = 0.15, \quad \eta_{wood} = 0.10$$

The efficiency of solar collectors is difficult to accurately model. An online calculator³⁹ for efficiencies of various professionally made solar collectors showed that an high-end solar collectors (unglazed) have an efficiency of 0.3 when the collector is 50°F hotter than the ambient temperature. The efficiency of low-end solar collectors in the developing world were approximated to be roughly half this value due to lower quality reflective material and poorer focusing.

$$\eta_{solar} = 0.15$$

The resulting power requirements from each heating source are shown in Table 3 and Fig. 9.

Table 3 | The heater's power output for each heating source was calculated based on the required power input ($Q_{absorbed}$) and the stove efficiency (η_{source}). The power required for electricity, propane and kerosene are very similar, but solar, charcoal, and wood are require much more power because they are very inefficient heating methods.

Heat Source	Electricity	Propane	Kerosene	Charcoal	Wood	Solar
Stove Efficiency ^{35,36}	0.70	0.50	0.40	0.15	0.10	0.15
Heater Power Output for 4L Cooker [kW]	0.63	0.88	1.11	2.95	4.42	2.95
Heater Power Output for 23L Cooker [kW]	1.14	1.60	2.00	5.33	8.00	5.33

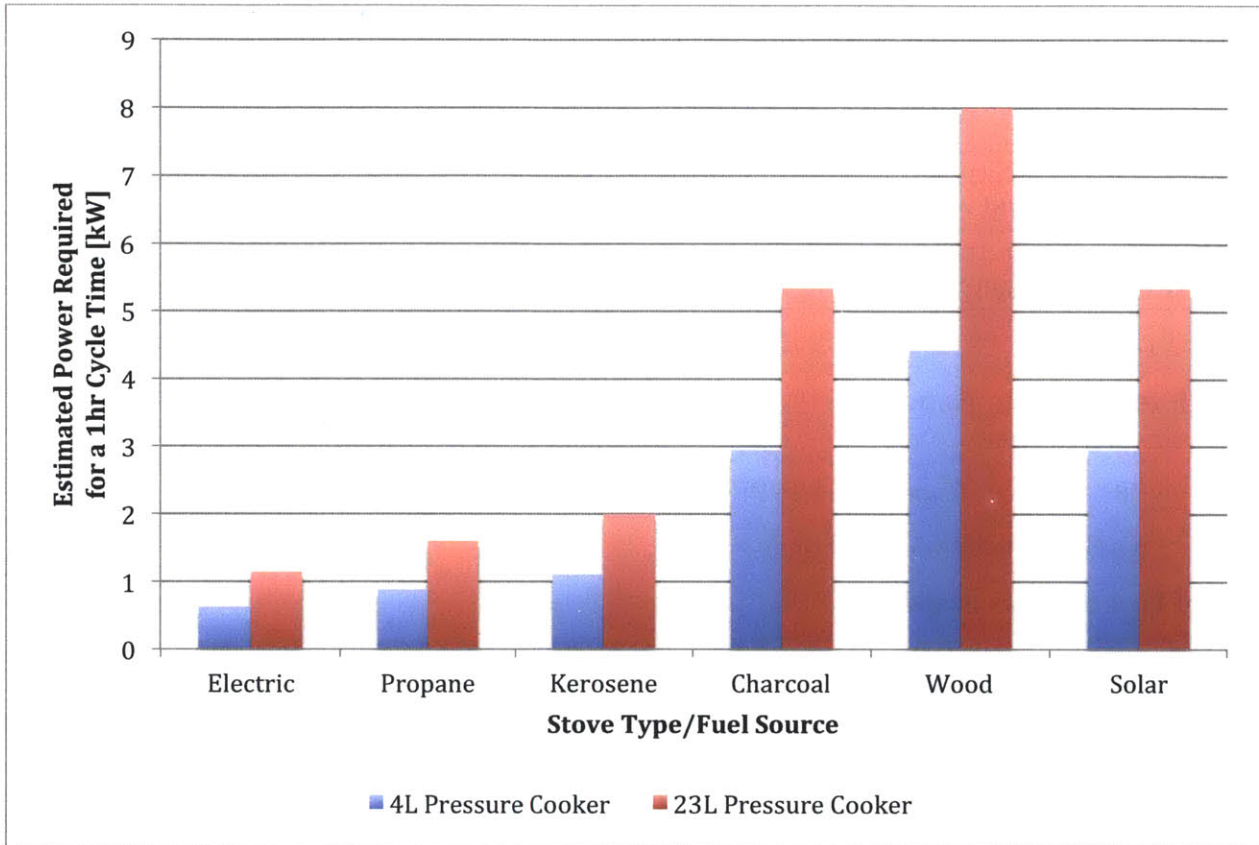


Figure 9 | The required heater power output for each fuel sources is shown. It is important to note that a particular stove may not be able to deliver these powers and subsequently fail to achieve boiling in 30 minutes. A very large wood stove is required to deliver 8kW. Most low-end electric stoves found in the developing world (resistive heating coil only) can output 0.5-0.7kW and would be unable to power the large pressure cooker, even for an infinite heating time. Conversely, propane and kerosene stoves are typically rated around 3kW (10,000 BTU), which is well above the power required for even the largest pressure cooker.

3.1.4 Estimated Energy Required for Each Autoclave Cycle

Each cycle takes approximately 1 hour: 30 minutes of heating and 30 minutes of boiling.

The energy required from each heating source for an entire autoclave cycle is constant power output from the heater multiplied by the time over which that power is delivered (1 hour).

$$E_{cycle} = Q_{source} \cdot t_{cycle} \quad (30)$$

Table 4 | The total fuel energy expended per cycle is calculated based on the power is directly proportional to the required power from the heating source because the fuels are delivered over the same amount of time.

Heat Source	Electricity	Propane	Kerosene	Charcoal	Wood	Solar
Heater Energy Output for 4L Cooker [kWh]	0.63	0.88	1.11	2.95	4.42	2.95
Heater Energy Output for 23L Cooker [kWh]	1.14	1.60	2.00	5.33	8.00	5.33

3.1.5 Fuel Costs in Nepal

Necessary conversions

NPRs = Nepali Rupees, ~80NPRs/1USD

3.6 MJ = 1kWh (kilowatt hour)

Cost of Fuel Inputs in Nepal

Propane can (15kg/can): $\sim 1500 \frac{\text{NPR}}{\text{can}} = 18.75 \frac{\text{USD}}{\text{can}}$

Kerosene (per liter): $\sim 70 \frac{\text{NPR}}{\text{L}} = 0.88 \frac{\text{USD}}{\text{L}}$

Electricity (per kWh): $7.3 \frac{\text{NPR}}{\text{kWh}} = 0.09 \frac{\text{USD}}{\text{kWh}}$

Cost of Propane (per kWh)

$$\frac{18.75\text{USD}}{\text{propane can}} \cdot \frac{\text{propane can}}{15\text{L propane}} \cdot \frac{1\text{L propane}}{0.493\text{kg}} \cdot \frac{1\text{kg propane}}{43\text{MJ}} \cdot \frac{3.6\text{MJ}}{1\text{kWh}} = 0.21 \frac{\text{USD}}{\text{kWh}} \quad (31)$$

Cost of Kerosene (per kWh)

$$\frac{0.88\text{USD}}{1\text{L kerosene}} \cdot \frac{1\text{L kerosene}}{33\text{MJ}} \cdot \frac{3.6\text{MJ}}{1\text{kWh}} = 0.10 \frac{\text{USD}}{\text{kWh}} \quad (32)$$

Cost of Coal (per kWh)

$$\frac{\sim 100\text{USD}}{2000\text{ lbs}} \cdot \frac{2.2\text{ lbs}}{1\text{ kg}} \cdot \frac{1\text{kg}}{6.67\text{kWh}} = 0.02 \frac{\text{USD}}{\text{kWh}} \quad (33)$$

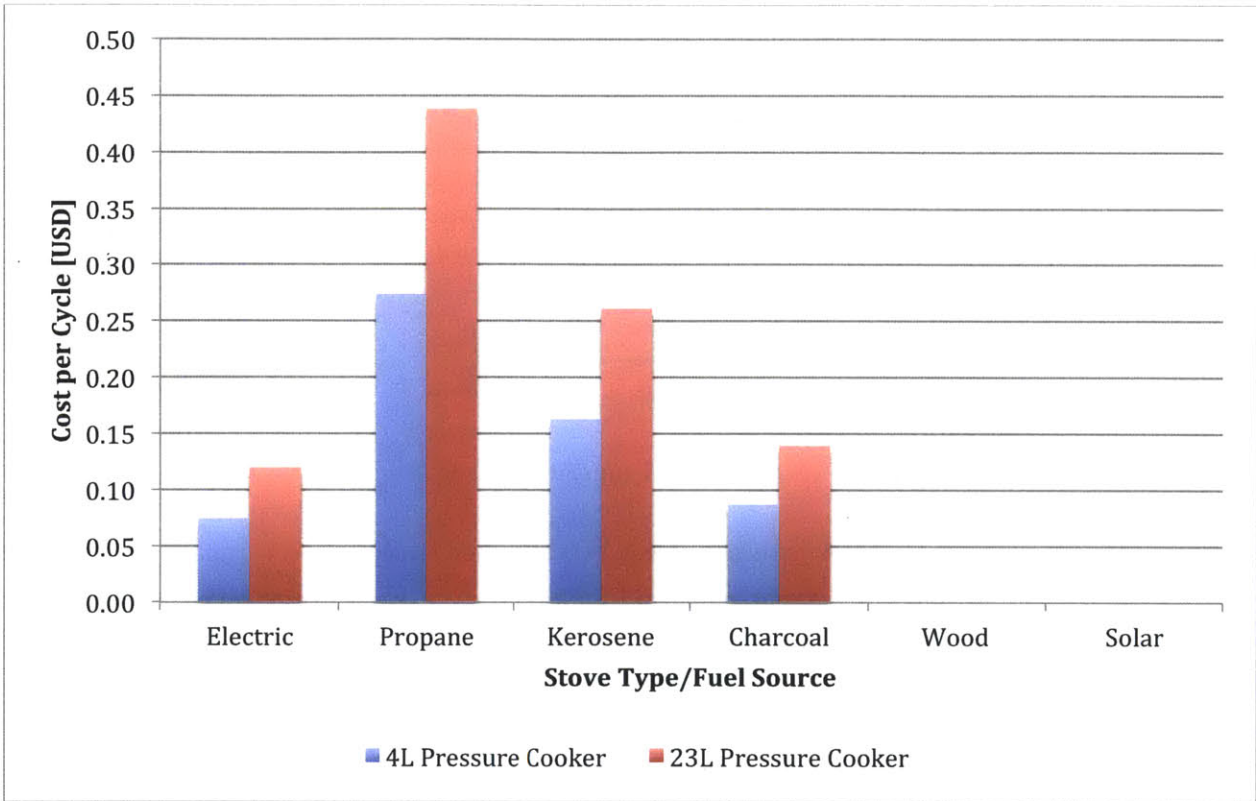


Figure 10 | The cost per cycle is shown for local fuel prices in Nepal. The fuel cost is highest for portable fossil fuels (propane, kerosene) and lowest for the most labor-intensive energy sources (wood, solar). Wood is free because it is collected by hand in Nepal and rarely if ever purchased. It is also important to note that these are only fuel costs and ignore the ongoing maintenance costs required to keep the different stoves operable. Maintenance costs would most likely be lowest for electricity, propane and kerosene.

3.1.6 Fuel Weight and Volume per Cycle

The weights and volumes were calculated based on the energy required per cycle, the energy density, and the material density.

$$m_{fuel} = \frac{E_{cycle}}{u_{fuel}} \quad (34)$$

$$V_{fuel} = \frac{m_{fuel}}{\rho_{fuel}} \quad (35)$$

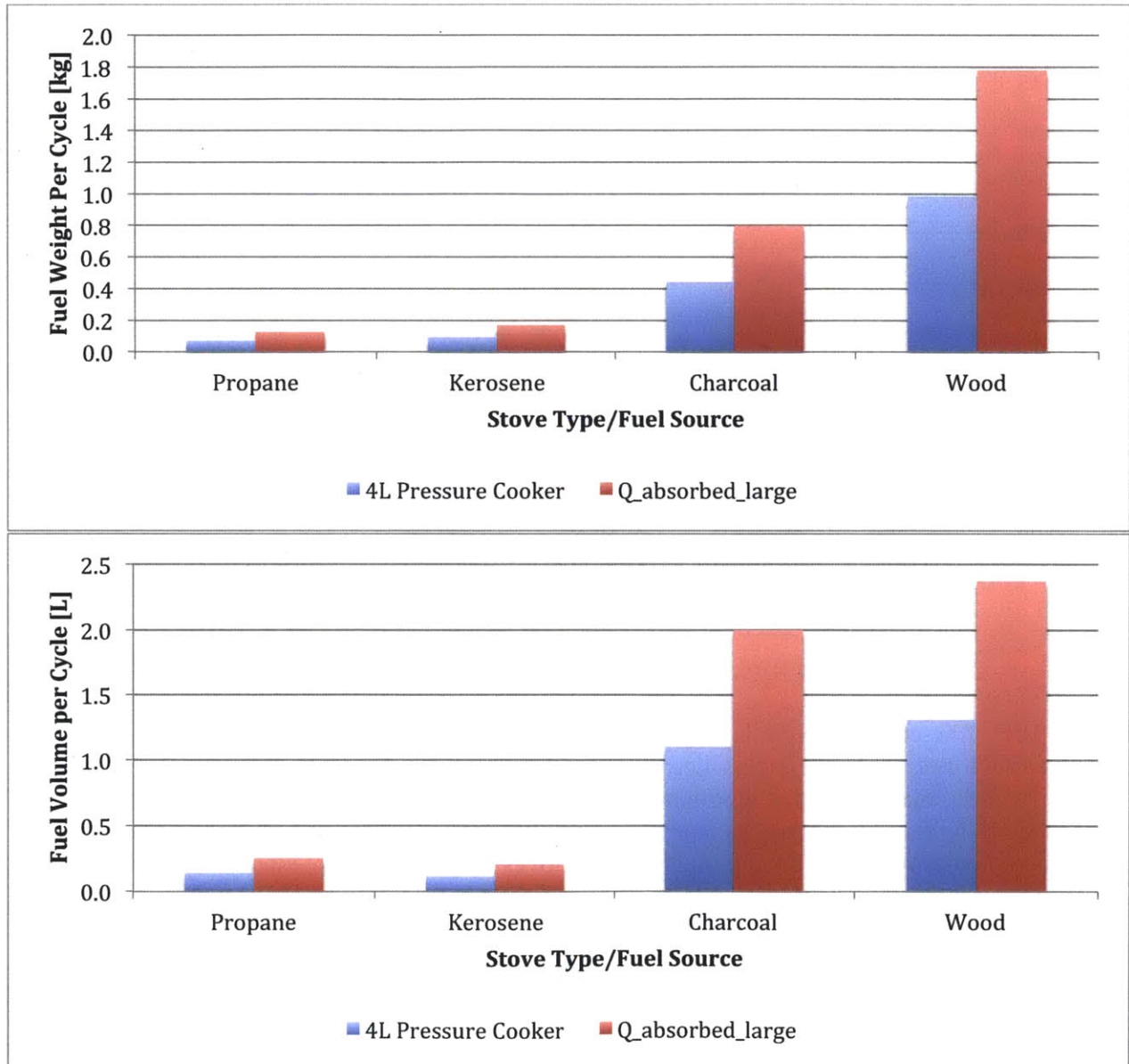


Figure 11 | The fuel weight/volume of combustible fuels in the developing world are shown to compare their relative amounts required per autoclave cycle. The propane and kerosene required would fit inside a can of soda. Conversely, the volumes of charcoal or wood are closer to a gallon of solid fuel and are much heavier.

3.1.7 Minimum Solar Collector Size

The total energy received by a solar collector is

$$P_{solar\ collected} = A \cdot q_{sun} \quad (36)$$

where A is the projected area orthogonal to the sun's rays. Based on the solar collector efficiency of 15% and a heating time of 30 minutes, the required power from the solar collector must be

$$P_{solar\ collected} = \frac{Q_{absorbed}}{\eta_{solar}} = \frac{442W}{0.15} = 2.95\ kW$$

The maximum heat flux on earth's surface from the sun's radiation⁴⁰ ($q_{sun,max}$) is $1.36 \frac{kW}{m^2}$, but $1.00 \frac{kW}{m^2}$, is a more accurate real-world estimation. From this minimum collected power (21) required for a 30 minute time to boil, the solar collector area can be solved:

$$A_{min,4L\ cooker} = \frac{Q_{collector}}{q_{sun,max}} = \frac{2.95\ kWh}{1kW/m^2} = 2.95m^2 \quad (37)$$

$$A_{min,23L\ cooker} = \frac{Q_{collector}}{q_{sun,max}} = \frac{5.34\ kWh}{1kW/m^2} = 5.34m^2 \quad (38)$$

One might argue that this is excessively large since the solar collector can remain outside for many hours. We can therefore assume best case conditions for a solar collector. The maximum reasonable heating time with a solar collector is around 4 hours.

$$P_{solar\ collected} = \frac{Q_{absorbed}}{\eta_{solar}} = \frac{225W}{0.15} = 1.5kW$$

$$A_{min} = \frac{Q_{collector}}{q_{sun,max}} = \frac{1.5\ kWh}{1kW/m^2} = 1.5m^2$$

It is important to note that this collector size assumes perfect weather conditions with absolutely no clouds ($1.00 \frac{kW}{m^2}$ over the entire 4 hours) and continuous maximum efficiency ($\eta_{collector} = 0.15$) from perfect focusing over the entire 4 hours.

There are various countermeasures that can decrease the collector area. These include to improved reflective material to increase efficiency and wider acceptable "viewing angles" to increase the acceptable operator error. Regardless, the following fundamental tradeoffs are inherent to any solar collector used for immediate heating:

- Efficiency vs. cost (quality of reflector material)
- Efficiency vs. focusing tolerance (collector geometry)
- Heating time vs. ease of use (collector size)

Table 5 | The calculations for heater power, fuel weight per cycle, and fuel cost per cycle are summarized here for the small, 4L pressure cooker.

Fuel Source	Electric	Propane	Kerosene	Charcoal	Wood	Solar
Heater Efficiency	0.70	0.50	0.40	0.15	0.10	0.15
Heating Power [kW]	0.63	0.88	1.11	2.95	4.42	2.95
Energy per Cycle [kWh]	0.63	0.88	1.11	2.95	4.42	2.95
Energy Density [kWh/kg]	-	12.89	11.94	6.67	4.50	-
Material Density [kg/L]	-	0.49	0.82	0.40	0.75	-
Fuel Weight	-	0.07	0.09	0.44	0.98	-
Fuel Volume	-	0.14	0.11	1.11	1.31	-
Cost per kWh [USD]	\$0.08	\$0.21	\$0.10	\$0.02	\$0.00	\$0.00
Cost per Cycle	\$0.05	\$0.19	\$0.11	\$0.06	\$0.00	\$0.00

Table 6 | The calculations for heater power, fuel weight per cycle, and fuel cost per cycle are summarized here for the large, 23L pressure cooker.

Fuel Source	Electric	Propane	Kerosene	Charcoal	Wood	Solar
Heater Efficiency	0.70	0.50	0.40	0.15	0.10	0.15
Heating Power [kW]	1.14	1.60	2.00	5.33	8.00	5.33
Energy per Cycle [kWh]	1.14	1.60	2.00	5.33	8.00	5.33
Energy Density [kWh/kg]	-	12.89	11.94	6.67	4.50	-
Material Density [kg/L]	-	0.49	0.82	0.40	0.75	-
Fuel Weight [kg]	-	0.12	0.17	0.80	1.78	-
Fuel Volume [L]	-	0.25	0.20	2.00	2.37	-
Cost per kWh [USD]	\$0.08	\$0.21	\$0.10	\$0.02	\$0.00	\$0.00
Cost per Cycle	\$0.09	\$0.34	\$0.20	\$0.11	\$0.00	\$0.00

3.1.8 Energy Source Pugh Chart

Table 7 | The fuel sources are systematically compared in this pugh chart based on quantitative metrics (i.e. cost, fuel weight), supply chain robustness, and ease of operation. Propane and kerosene are the most desirable fuel sources in Nepal and worldwide because they have a high power density and efficient stoves. Propane and kerosene are also reliable and easy to use but cost the most. Solar heating has the lowest score by far because it is highly weather dependent, requires an enormous collector, and requires continued supervision and maintenance. Any fuel source (excluding solar) could easily rank first if it is the sole reliable and readily accessible fuel source in a particular geographic region. Very similar pressures on the cooking fuel have shaped the heating fuel supply over decades throughout the developing world, making the prevalent cooking fuel a good predictor of the most appropriate local fuel source. A system that is flexible enough to accept a variety of heating sources is therefore extremely advantageous when seeking a design with a potential for global scale. The autoclave product architecture designed here is a simple pressure cooker that can be powered by any heating source.

Evaluation Metrics	Electric		Propane		Kerosene		Charcoal		Wood		Solar	
Quantitative metrics												
Fuel Weight/Volume	-	0	0.14	+	0.18	+	0.87	-	1.93	-	-	0
Fuel Cost per Cycle	\$0.07	+	\$0.27	-	\$0.16	-	\$0.09	+	\$0.00	++	\$0.00	++
Operation Time	1hr	0	1hr	0	1hr	0	1hr	0	1hr	0	1hr	0
Heater Size	small stovetop element	+	small stovetop burner	+	small floor burner	+	Medium floor stove	0	Large fire pit	-	enormous collector (5.6m ²)	---
Supply												
Reliability of Supply (in Nepal)	frequent power outages	--	always available	++	always available	++	readily available	++	readily available	++	weather dependent	-
Availability of Supply (in Nepal)	widely available	+	available everywhere	++	available everywhere	++	not available	---	available	+	weather dependent	-
Ease of Use												
Probability of Fuel Shortage	medium	0	low	+	low	+	low	+	low	+	high	-
Supervision Level	low	+	low	+	low	+	medium	0	medium	0	high	--
Maintenance	low	+	low	+	medium	0	medium	0	low	+	high	-
Total	+3		+8		+7		+2		+5		-7	

3.2 SYSTEMS LEVEL DESIGN – STAKEHOLDER ANALYSIS

Adoption and sustained usage are central goals of the autoclave project, but scalability is also fundamental to maximizing impact – a central tenant of all development work. Inputs from many stakeholders other than the end user – buyers, manufacturers, and repairmen – were important to consider early in the design process, as their interests often conflict but all greatly influence the probability of scaling success. For example, government buyers typically disregard usability features as superfluous whereas end users consider these features indispensable. Also, manufacturers tend to add extra features to increase their profit margins, but the buyers' purchasing heavily favor the lowest cost item.

An initial set of stakeholder needs was created before designing the first autoclave iteration, (Table 8). Needs were collected directly from the stakeholder when possible, but assumed by researchers if the stakeholder was inaccessible. During the field trial over the summer of 2011, these stakeholders were all interviewed extensively to better understand their incentives and needs. An easy to use, low-cost, mass-manufacturable, and profitable product design was pursued to fulfill each of the stakeholders' unique interests and incentives (Fig. 12). Government buyers, manufacturers, and distributors were targeted for further interviews while in the field.

Table 8 | Autoclave design requirements from specific stakeholders were identified before designing the first prototype.

* based on consultations with advising Nepali students

** assumed by designers

Design Requirements	Stakeholder
Hardware-oriented	
Safe (from explosions)	User
Robust/repeatable	User
Flexible Heating Source	User
Operate with long-term power outages*	User/Buyer
Portable**	User/Distributor
Mass-manufacturable**	Manufacturer
Low-cost*	Buyer
Profitable**	Manufacturer
Use-oriented	
“Easy to use/read”**	User/Buyer
Clear success/fail indication*	User/Buyer
Repair/maintenance**	User/Buyer

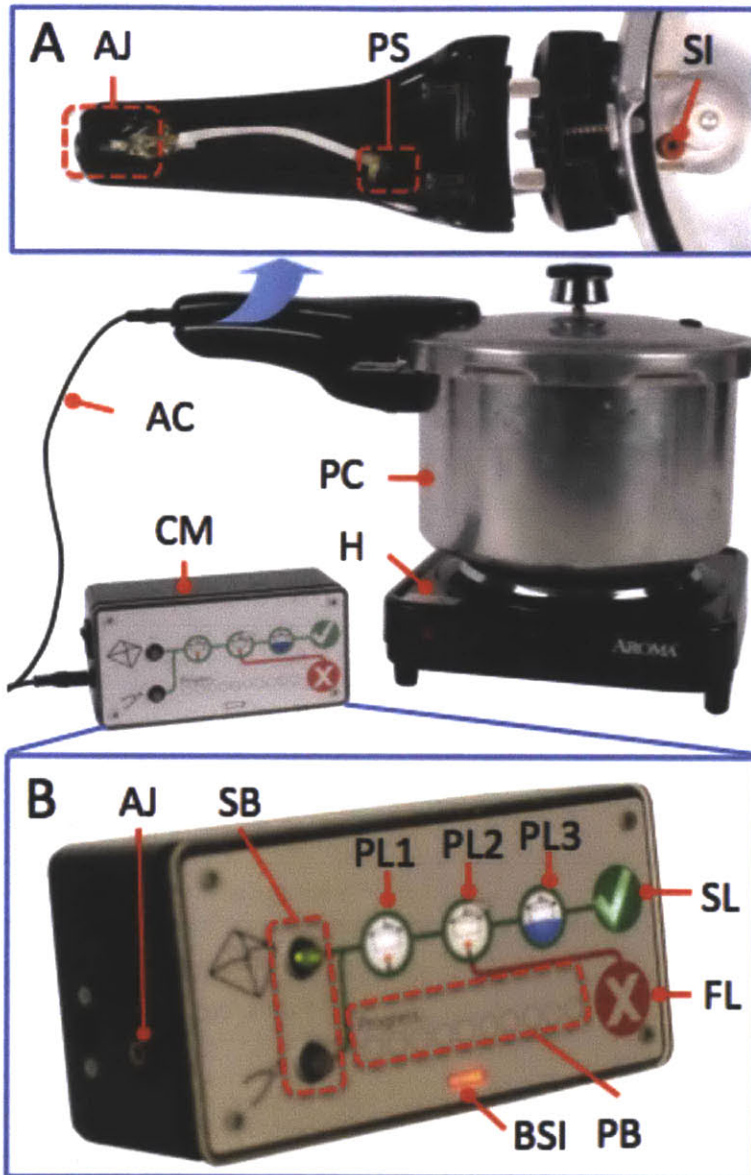


Figure 12 | The autoclave product architecture includes a heating element, pressure cooker, pressure sensor, and cycle monitor. The sensor and cycle monitor increase the convenience of the autoclaving process as compared to other autoclave designs.

Inset A | The pressure sensor is integrated into the handle and monitors the internal pressure through a tube.

Inset B | The cycle monitor reads the internal pressure from the sensor and relays information to the user via backlit graphics and a speaker. The user selects whether instruments are wrapped in linens or not using the select buttons. The user is then guided through the autoclave process via the phase lights and progress bar. Finally, cycle success or failure is indicated by the check and X lights.

Labels | AJ-audio jack, PS-pressure sensor, SI-sensor inlet; AC-audio cable, CM-cycle monitor, PC-pressure cooker, H-heater; SB-select buttons, PL1/2/3-heating/steam/cooling phase lights, BSI-battery status indicator, PB-progress bar, SL-success light, FL-fail light

3.2.1 Design for User

Nepalese students at MIT were able to utilize their personal networks to identify and screen interested clinics in Nepal. Partnering clinics were consulted to understand the clinical environment and competing devices. We learned that instruments were autoclaved in hospitals but boiled in RHPs, even though pressure cookers, a tool fit for autoclaving, were in use in nearby kitchens. Our Nepali student advisors had no idea that a pressure cooker could be used as an autoclave, and we realized that people had a hard time making the mental leap because of product perception. The advisors also warned that autoclaving, taking approximately 1 hour, was far less convenient than boiling for 15 minutes, the prevailing substitute. The team concluded that a comprehensive solution to improve product perception and maximize convenience was necessary.

We designed our product architecture (Fig. 12) around the existing autoclave infrastructure – a pressure cooker and any local heating source used for cooking. These components take advantage of embedded knowledge of pressure cooker operation in context of cooking and utilize existing supply chains for fuel, heating units, and pressure cookers. In addition, small washers were added to the dead-weight pressure regulator to account for decreases in ambient pressure from high elevations, ensuring that 203kPa – and 121^oC needed for sterilization would still be achieved.

The cycle monitor and pressure sensor were added to improve product perception, convenience, and adherence to the correct autoclave protocol. The Nepali advisors said staff in the developing world typically follow ritualistic protocols that are often ineffective. The pressure sensor (Fig. 12, inset A) monitors the internal conditions of the pressure cooker and relays that information to the cycle monitor (Fig. 12, inset B), which guides the user through the correct

protocol every cycle. Users receive feedback on successful or failed cycles every time the device is used via backlit success and fail graphics. The cycle monitor also makes the process convenient by using embedded ringtones to only alert users for their attention when it is required. The electronic cycle monitor was designed to look and feel like a professional medical product to clearly delineate the system from pressure cookers for cooking.

3.2.2 Design for Buyer

Prospective autoclave buyers included the Nepali ministry of health, NGOs, and individual public and private clinics. Purchasing decisions were assumed to be highly price elastic, heavily favoring low-cost options, as is typical of developing world buyers in general. However, there were significant gaps in the team's knowledge of the ministry of health's funding distribution (central vs. local), budget sizes, or formal procurement procedures.

3.2.3 Design for Manufacture

Incorporation of a commoditized input, pressure cooker, and eliminating integration of the heating source accelerated prototyping, reduces costs and removes dependence on the inconsistent electric grid. Pressure cookers and heaters, such as gas stoves and open fires, have established supply chains making them widely available in the developing world. The cycle monitor and pressure sensor module utilize electronics that can easily be mass-manufactured and enclosure materials and designs that can be injection molded.

3.2.4 Design for Repair

Commoditized pressure cooker and heater inputs also simplify sourcing repair parts. It was assumed that most people would be able to service the pressure cooker as it is a common household device. However, the cycle monitor required a more complex set of skills and tools for repair. It was assumed that these were not available and that onsite repairmen would be required.

3.3 MECHANICAL AND BIOLOGICAL TESTING

Initial testing was performed, using the experimental setup (Fig. 13), to ensure the boiling point increased with pressure and that the appropriate temperature and pressure could be maintained for 30 minutes at different pressures. These tests were carried out using thermocouples⁴¹ spread throughout the inside of the pressure cooker and a pressure sensor connected to internal cooker conditions via a PTFE tube. Test results show that pressure and temperature are linked once boiling is achieved and that conditions exceed the 121^oC and 202kPa threshold required by the CDC standards for sterilization (Fig. 14).

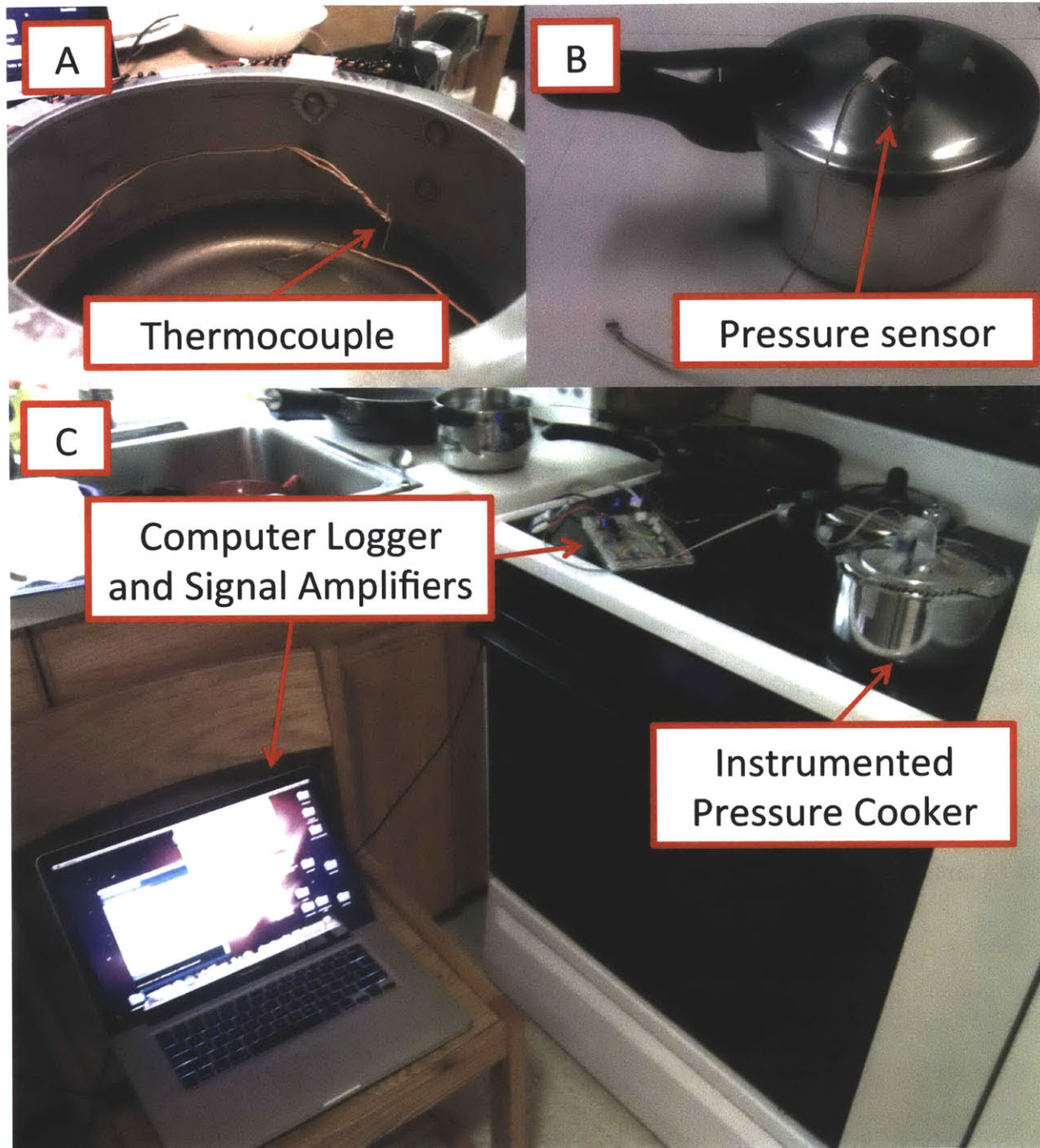


Figure 13 | This test setup was used to test early prototypes to ensure they met the correct pressure and temperature threshold values outlined by the CDC – 2atm and 121^oC. The steam pressure and temperature inside the pressure cooker were measured via thermocouples (A) and a pressure sensor (B). The entire experimental protocol (C) was run on an electric stove (~2kW).

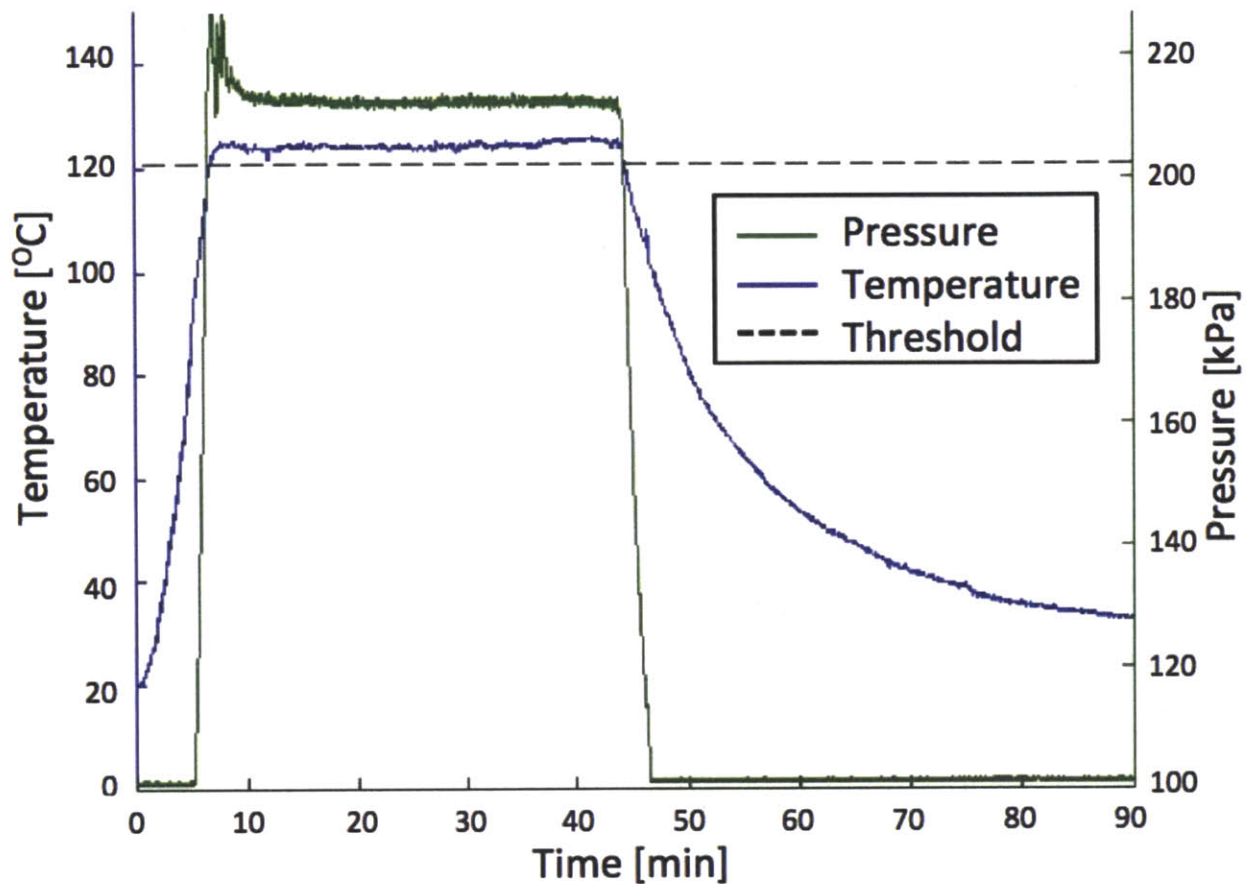


Figure 14 | Pressure and temperature from autoclave validation testing show values above 121°C and 203kPa for >30min, the required exposure conditions outlined by the CDC sterilization specifications³¹. The mean pressure within the flat region above the threshold was calculated for each trial (n=19). The collective mean pressure was 214.59±4.32 kPa. The mean of the pressure variance in this region was 0.049 +/- 0.107 kPa. The mean overshoot past the flat, steady-state pressure was 5.93±1.97 kPa.

Twenty final autoclave units were extensively tested using both mechanical and biological methods before release into the field. The pressure was recorded throughout the cycle for each of the autoclaves to ensure that the appropriate pressure was maintained for 30 minutes. 3M Attest biological indicators (3M-1262)⁴², containing the non-pathogenic *G. Stearothermophilus* endospore, are the industry standard for testing steam autoclave efficacy. Two 3M spore vials were placed in each autoclave with one wrapped in an instrument pack and the other placed anywhere outside the pack (Fig. 15). These vials were incubated after one autoclave cycle at 56°C for 48 hours in an incubator (3M-116). If the autoclave failed to reach the appropriate SAL, living spores within the vial multiply when incubated, turning the colorimetric media yellow; however, the media remains purple in the absence of living spores, which indicates a successful autoclave cycle. All autoclave cycles yielded successful, purple biological indicators after incubation meaning a sterile environment (SAL of 10⁻⁶) was achieved.

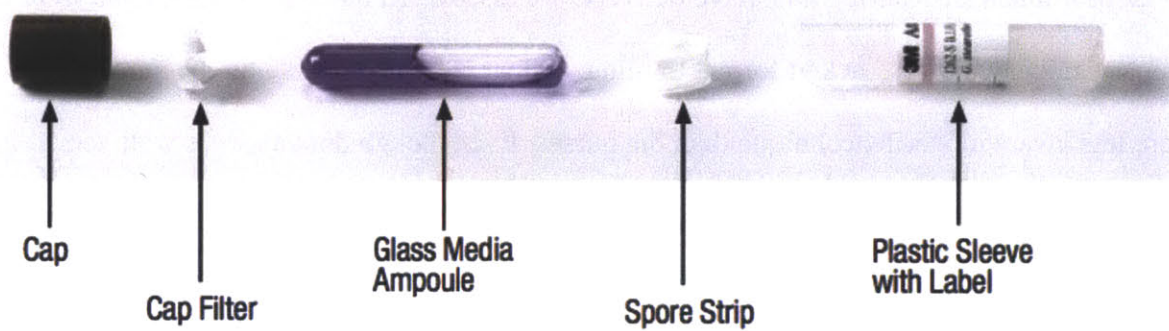
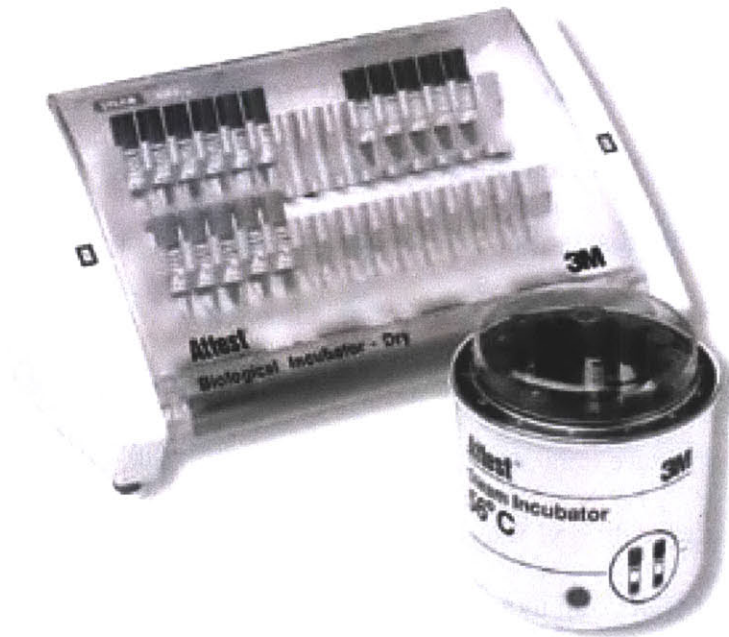


Figure 15 | The vial (below) contains *G. Stearothermophilus* endospores on a strip and pH sensitive media that changes color to yellow if surviving spores multiply and change the pH of the medium. However, no spore survival will cause the media to remain at the same pH and stay purple. The spore vials are run through a steam autoclave cycle just like medical instruments. The vials are then cracked as they are inserted into the incubator (above) to expose the spore strip to the purple media. Incubation for 48hrs at 56°C yields a binary result (sensitivity of 95%) of either cycle success, purple, or cycle failure, yellow.

4 FIELD TESTING

4.1 DEVICE DELIVERY AND ADOPTION EVALUATION

Over the summer of 2011, fifteen autoclaves were delivered to Nepali healthcare facilities that had given verbal commitment to use the autoclave. These facilities included RHPs (outpatient), small private clinics (outpatient), dental clinics, as well as urban and rural hospitals (>40 beds, inpatient). A variety of facilities were visited to help identify the best-fit facility demographics and tailor future iterations to their unique needs. Follow-up interviews were conducted one month after delivery. We returned to Nepal during a second trip in the winter of 2011 to conduct another follow-up interview six months after delivery and get feedback on our second iteration of the autoclave described in section 5.1.

In user interviews during autoclave delivery, we discovered that nurses' assistants were the primary autoclave users, lacked formal training, and were trained on site by the nurses. They were less aware of sterile technique than the nurses. Even though doctors were well versed in sterile technique and understood the clinical value of an autoclave, their knowledge rarely trickled down to the nurses' assistants. We therefore identified the need to clearly explain the autoclave's clinical value versus boilers to RHP staff to drive initial adoption. Standard autoclave operation protocols and additional sterile technique (pre-cleaning, handling of sterile instruments, etc.) were explained while utilizing a graphic-based paper instructions that were left with operators.

Unfortunately, nurses' assistants were hesitant to speak freely with us in the presence of a superior for fear of a superiors' disapproval. This necessitated segregation of the operator from superior clinic staff during some training and especially during later follow-up interviews.

Upon conclusion of device delivery, users were given usage survey forms to fill out periodically and a contact number of a local volunteer who would visit to collect paperwork and conduct maintenance. Usage data were collected for the six-month period following autoclave delivery. At one and six months post-delivery, sustained use and operator understanding were evaluated through a teach-back where users were asked to teach us their autoclave operation protocol. Co-design principles – emphasizing collaborative design ideation and evaluation – were also employed at one and six months to critique the design and learn what features the users liked and disliked as well as how the autoclave caused any shift in their daily duties. Cumulative results for sustained adoption are presented in Fig. 16.

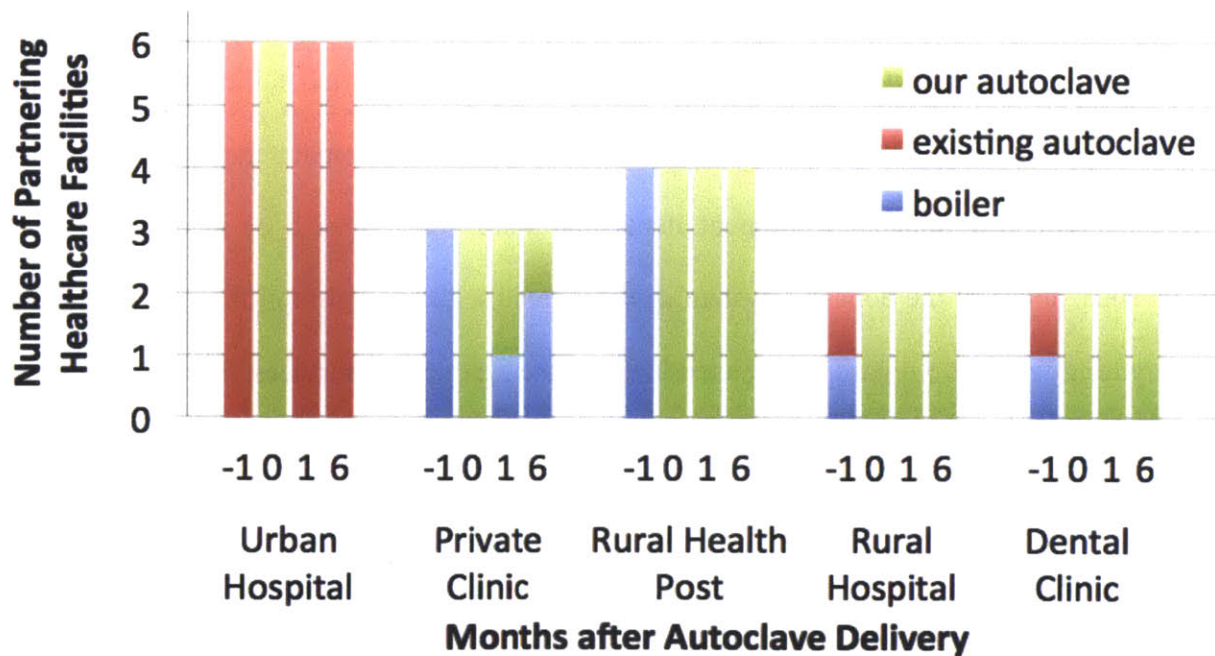


Figure 16 | Autoclave use was measured at each partnering clinic before delivery (-1), during delivery (0), and one (1) and six (6) months post-delivery. All autoclaves were successfully adopted in rural hospitals, RHPs, and dental clinics where our equipment was the primary autoclave and staff were highly motivated. In most private clinics and all urban hospitals, autoclave use was suspended due to low surgical patient volume and inconvenience, respectively.

We found that some participating clinics were not diligent about paperwork and in one case, it was clear that the data were false. Inaccuracies of self-reporting affected the data; however, observed trends still show interesting results. The following trends were first identified in these data and confirmed during the second visit: discontinued use was highly correlated with device failure (typically easy to repair) and users were very confident about their ability to operate the device properly.

4.2 THE DONOR CULTURE

The Nepali government receives a significant amount of foreign aid and individual facilities, especially in the healthcare sector, receive support and donations from international NGOs (iNGOs). These iNGOs are known for donating equipment and failing to identify the lasting value of their donation via follow up interviews or continued maintenance. Every clinic we visited had a few donated equipment items that were either unused or in disrepair from neglect. Thus, abuse of the donation system is widespread with local groups asking for anything and everything with little regard to the usefulness of the products or services. The true utility of the donations are only evaluated after the donors left. The team encountered this when speaking with RHP staff who would ask for anything and everything they thought we could provide.

Researchers presenting the appearance of a “foreign aid” project or affiliation elicit significant bias from our partners in Nepal. Factors that made the team not look like a foreign aid project were our appearance (I apparently look Nepali), team fluency in Nepali, and our dress. Nonetheless, we were donating a device, and I was pegged as American from the moment I spoke. As a result, many healthcare facilities agreed to use our autoclaves, but upon revisiting,

less than half had been used even once. These healthcare facilities were also surprised that we had revisited and were certainly not expecting us to follow up with them, as many aid agencies never do. Throughout the next month, our team followed up with these healthcare facilities multiple times, pulling the device out of six large hospitals that had promised to use the equipment but never did because it was inconvenient as compared to the large, automatic autoclaves they had.

4.3 FIELD INTERVIEWS AND OBSERVATIONS

The findings below are the result of observing and interviewing partners in the field.

4.3.1 User

Follow-up interviews were conducted with the nurse's assistants operating the autoclave at six month post-deliver when operators had time to integrate the autoclave into their normal routine. The respondents were asked what features they liked and disliked about the autoclave and to rank their importance. Every respondent (n=9) ranked the autonomy and reassurance of full instrument sterility provided by the cycle monitor as the first or second most important. Pressure vessel safety and ease of use were the next most important factors from all respondents. These results show that the cycle monitor was extremely important to clinical staff and added significant value to their daily activities.

During teach-backs and general observation at one month post-delivery, we observed incomplete adoption of appropriate autoclave use procedures, typically due to misunderstanding the instructions and not a lack of motivation. Improper instrument preparation and non-sterile handling following the autoclave cycle also necessitated repeated reinforcement to ensure sufficient instruments cleaning after autoclaving. These challenges were minimal at rural

hospitals, where doctors and other highly educated medical professionals were available for consultation; however, RHPs lacked anyone with more than a nurse's certificate and were slow to adopt the appropriate techniques, even with our continued guidance and multiple follow-up visits. The lack of training efficacy was confusing as we provided onsite demonstrations, easy to read autoclave instructions, and ready access via phone to our team of autoclave experts. We were also verbally reassured multiple times by our partners that they understood the protocols and would strictly follow the protocols. This level of training far exceeded the quality and length of government workshops that train RHP staff on new techniques, but was still only able to achieve full compliance after multiple in-person follow-ups. These training failures highlight the need for effective instructions that are extremely easy to understand and are convenient to follow.

4.3.2 Buyer

The Director General of logistics in the Nepali Ministry of Health is in charge of all medical equipment and pharmaceutical procurement for all government-run hospitals and RHPs, controlling funds for all large purchases over ~\$30 USD. These purchases are made for bundled equipment, so a full solution including the pressure cooker and the monitor is required. His buying decisions are based primarily on cost, perceived robustness, warranty, and repair services. There are no regular channels of communication between this minister and the RHPs, which de-emphasizes the importance of usability in his purchasing decision. He recommends a market price less than \$250 USD, a product lifetime of at least five years, and a warranty period of one year or more. His inputs are especially important because autoclave adoption at the national level is needed to generate ample demand to reach economies of scale.

RHP staff were also consulted for their purchasing decision. They stated that their discretionary funding budget was very limited and routed through local government officials. This money typically purchased gauze or small consumables, and all capital equipment and medications were purchased in bulk and dispensed nationally by the central government. The RHP protocol to acquire equipment involved submitting a formal request to the ministry of health that frequently go unfulfilled. Rural hospitals and private clinics had a larger discretionary budget and shopped for equipment in small surgical shops. The independence of these facilities make them hard to target in large numbers. A procurement system involving a multitude of stakeholders was mapped (Fig. 17).

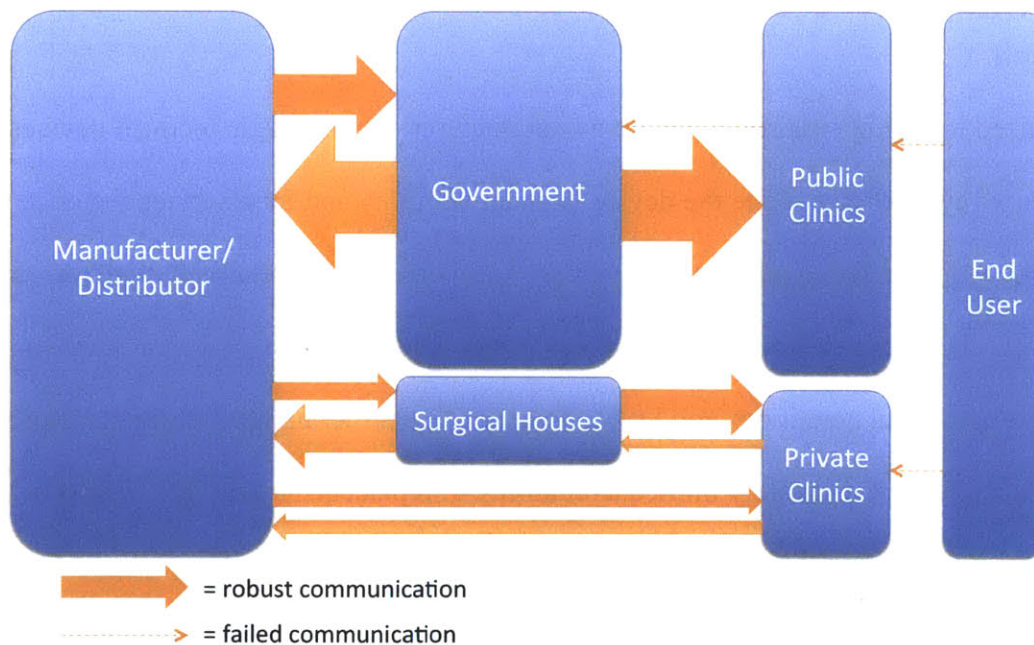


Figure 17 | The medical procurement chain consists of government (top) and private (bottom) procurement chains. Arrow size is proportional to the health of communication between the two parties. Solid arrows represent functioning communication channels and, dashed arrows represent significantly hindered or failed communication channels. Market players that exchange money (government, manufacturer, surgical houses, private clinics) have very good levels of communication. However, communication is very poor and not well monitored where only goods and/or training are exchanged. Failure of these communication channels typically occurs from hierarchical structure (bosses not wanting to listen to their employees) or poor training techniques.

4.3.3 Manufacturer

The industrial manufacturing base in Nepal is virtually non-existent. Nepal is not only neighbor to two manufacturing giants – India and China – but also saw significant erosion of its limited manufacturing infrastructure during political instability and civil war from 1996 to 2006. The vast majority of medical products in Nepal, including autoclaves, are made in India.

A small patient monitor manufacturer in India agreed to partner with us to mass-manufacture the electronic systems and their enclosures. This early partnership allowed us to make more informed design for manufacture decisions on later iterations. It has also allowed us to better understand the supply side market forces.

4.3.4 Repair

Specialized traveling repairmen service a manufacturer's high margin medical devices (i.e. ultrasounds, x-rays) for free while the device is under warranty and for a service fee once the warranty has expired. These repairmen have very specialized skills, relatively high pay, and simple travel schedules restricted to urban zones. They often refuse to visit rural locations because of rough travel conditions and low compensation. Partnering rural hospitals expressed deep displeasure with the severely limited availability of replacement parts and outright refusal by repair personnel to visit their facility.

Mobile phone repair shops were apparently widespread and had the required skills and tools required to fix minor electronic repairs. The cycle monitor and pressure sensor were designed to be very accessible for diagnostic and repair needs. More complex repairs require greater electric and mechanical skills as well as the appropriate tools and spare parts that could only be found at the manufacturing facility or a designated refurbishing facility. Major repairs would require

shipping the broken equipment and replacement equipment. Shipping would be easy for the small cycle monitor but harder for the pressure sensor module integrated into the pressure cooker handle. The optimal design would incorporate easily separable modules that could be safely attached and detached by RHP staff for assembly and repairs, respectively.

4.4 SUMMARY OF LEARNING FROM FIELD TESTING

Procedural Insights

- Users have a hard time thinking abstractly and creatively during design reviews and evaluations of non-functional prototypes.
- Users are not accustomed to filling out paperwork and many have difficulty reliably self-reporting information due to inconvenience and/or poor literacy.
- Staff power structure and cultural norms prohibit assistants from speaking their mind freely
-

Stakeholder Insights

Usage patterns and training

- The autoclave was used extensively in government-run RHPs and rural hospitals.
- The autoclave was donated but not used in urban hospitals and private clinics.
- RHP nurses and nurse's assistants have a poor understand of the difference between steam autoclaving and boiling.
- Increased safety and autonomy to do other tasks during the autoclave cycle were the most important benefits to our users.

- Improved training methods targeting nurse's assistants were needed to reinforce appropriate pre-cleaning and sterile instrument handling/storage.
- Users typically accept device failures and stop using the equipment rather than seeking repairs.
- The first version, equipped with only a buzzer, was difficult for users to understand, especially in infrequent events such as cycle failure.
- Users were very confident about their ability to operate the device properly after the six-months of use.

Buyer purchasing decision

- The purchasing decision is highly price elastic, as assumed.
- Usability is not a important to the buyer as it is assumed that users can be trained to understand and interact with any interface
- Perceived product longevity and warranty coverage are very important

Manufacturer

- There is no product manufacturing base in Nepal
- Medical products are almost exclusively imported from Indian manufacturers

Repair

- Skilled repairmen almost always refuse to visit rural locations
- Mobile phone repair shops are able to perform local repairs
- Components should be shippable for exchange of broken parts and/or major repairs at a central facility

5 REDESIGN

5.1 SECOND AUTOCLAVE ITERATION

The list of design requirements was revised to incorporate the lessons from the first prototype release over the summer of 2011 (Table 9). We confirmed the assumptions that the cycle monitor added indispensable value to operators and that the system fit best into RHPs and rural hospitals. Major alterations to the prototype include a need for improved training and detachable/shippable electronic modules for repairs.

Table 9 | Adjusted design requirements from interviewing the significant stakeholders and the exercise of delivering the first prototype. New additions are in red bold typeface and eliminations have a strikethrough line.

Design Requirements	Stakeholder
Hardware-oriented	
Safe (from explosions)	User/ Buyer
Robust/Repeatable	User/ Buyer
Flexible Heating Source	User/ Buyer
Operate with long-term power outages	User/Buyer
Portable Shippable Modules (sensor and monitor)	User /Distributor/ Repair
Easy assembly by operator	User/Repair
Mass-manufacturable	Manufacturer
Low-cost	Buyer
Profitable	Manufacturer
Warranty	Buyer
Use-oriented	
“Easy to use/read” and minimize user interpretation	User/ Buyer
Clear success/fail indication*	User/ Buyer
Repair/maintenance**	User/Buyer
Improved Training	User
High-resolution battery status indication	User
Operational	
Improved usage monitoring	researchers

The pressure sensor module and cycle monitor were redesigned - based on the aforementioned findings - with a heavy focus on training and minimizing user interpretation. The second design (Fig. 18) features voice instructions.

The new cycle monitor (Fig. 18, inset B) has voice prompts tell the user what to do, when to do it, when the cycle is finished, and if the cycle worked or not – mimicking the experience of always having an expert instructor present. It also includes instructions for instrument pre-cleaning and sterile handling at the end of the autoclave cycle. Verbal instructions eliminate the interpretation required to decode the meanings of various backlit graphics and ringtones from the first cycle monitor. Voice capabilities also allow the cycle monitor to convey more information with fewer lights and graphics, thereby reducing cost, and minimizing graphical clutter, which increases the intuitiveness of the interface. For example, the battery status LED and progress bar with various LEDs were eliminated and replaced by verbal notifications of percent charge and progress through each phase of the cycle. In addition, a built in tutorial standardizes the training experience to minimize instructor variability and to ensure that expert instruction is available even in remote regions. This training solution can be objectively tested and improved over time.

The novelty of these voice instructions to Nepalis cannot be overstated. The only electronics that talked in rural Nepali were the television and the radio. Doctors and staff were very excited about the new talking cycle monitor during our second trip. We also noted during our first visit that some of the clinics were located in loud settings or the room where the autoclave is located is far from where the user normally conducts his or her duties, in which case the alarms were not loud enough to actually give the user freedom to tend to other tasks. The second design comes with an auxiliary audio output that can connect to external speakers.

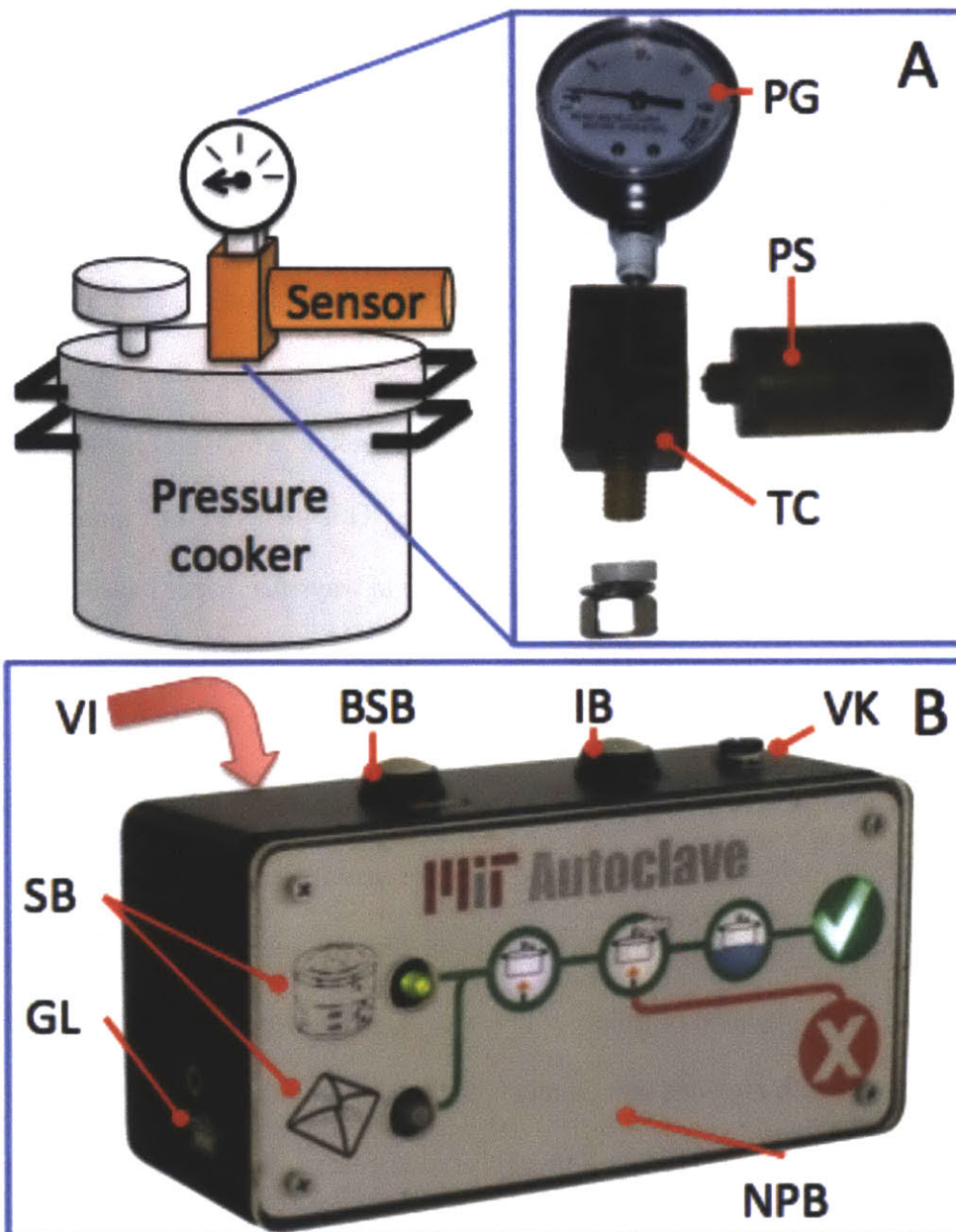


Figure 18 | A full redesign of the sensor module and iterative improvements to the cycle monitor make the second autoclave iteration more intuitive to use and easier to mass manufacture.

Inset A | The new sensor module can be attached to any pressure cooker or autoclave via a multitude of T-connectors. The sensor component easily unscrews for easy assembly and replacement.

Inset B | The new cycle monitor includes voice instructions (VI) and graphical tweaks to make the use more intuitive. The monitor also includes a full tutorial to standardize the teaching process and make expert instruction available in remote regions.

Labels | PG-pressure gauge, PS-pressure sensor, TC-T-connector; VI-voice instructions, SB-select button graphics, GL-graphic labels, BSB-battery status button, IB-instruction button, VK-volume knob, NPB-no progress bar

The sensor module (Fig. 18, insetA) was moved from an integrated position in the handle to a much more modular product architecture that now allows for quick yet secure attachment. This modularity makes removal and replacement that are required for repair very easy. The sensor module's varying T-connectors also make the sensor and cycle monitor compatible with many pressure cookers and existing autoclaves, where it can be sold as a modular addition.

Finally, an internal SD card used to store audio files is doubling as a data logger – recording relevant information about autoclave use. These metrics include which buttons are pressed, how frequently, and the pressure profile throughout the cycle. This gathered information will allow researchers to objectively and accurately measure usage in ways that paper based surveys cannot.

5.2 FUTURE WORK

Given the user feedback over the two staggered visits, we aim to further improve the autoclave's safety and autonomy features and design for manufacturability. We have partnered with an Indian industrial designer to explore new enclosure configurations to improve intuitive interaction design. Total physical redesign of the system will be conducted to address the potential safety issues with the wire that connects the sensor to the cycle monitor in the current design. Different alarms and speakers will be analyzed to ensure appropriate loudness and alertness. In addition to improved usability, we are working on a design that is scalable and cost-effective during production to attract buyers and increase manufacturer profitability.

I have also proposed the integration of cellular phone components into the cycle monitor to deliver usage data to researchers after every cycle. While data logging to the internal SD card is able to record objective usage data, that information is trapped in the field until the next field visit when the information can be retrieved in person. The cellular monitoring system would

allow researchers to track autoclave use in real time and, more importantly, flag non-use as an indicator of device failure or non-use.

6 CONCLUSIONS

A low-cost autoclave has been developed for RHPs in Nepal and the wider developing world to meet not only the technical requirements for sterilization, but also relevant social and business factors. The pressure cooker based design is grounded in sound autoclave theory; however, the design also addressed needs for ease of use to drive sustained adoption and mass manufacturability to increase potential for scale. The inclusion of both scientific and social/business factors allow the early stage product to address a holistic set of needs and evolve based on a systems perspective. This approach represents a broader view beyond human-centered design that has a narrow focus on the user. While the user is often the most important stakeholder, an isolated focus on the user alone neglects many other important stakeholder inputs and can lead to product evolution away from the needs of buyers, manufacturers, and distributors. Future iterations often require large steps backward to accommodate these other stakeholders's needs.

6.1 VALUE OF EARLY PROTOTYPING

The introduction of a functional prototype on our first visit clearly conveyed our purpose and catalyzed discussions and reviews with users not well versed in the creative design process. The prototype provided tangible value to a wide set of users, which got them excited about the process. We found that our user groups' design process was generally limited to choosing

between two commercially available products or implementing the first design to come to mind. The prototype helped extract latent needs through observation of actual use, which would be nearly impossible by abstract conversation alone.

An early focus on creating a usable and salable product led to a market-based approach that emphasized an understanding of a variety of potential users. Working with a large and diverse set of healthcare facilities helped us understand the wider market and identify the best-fit facility demographics for our autoclave. Rural, resource-limited facilities – RHPs and rural hospitals – were the most committed and compliant partners as the device added the greatest value for them. All urban hospitals already had a large autoclave, and although the large autoclave was frequently broken, it was more convenient, high-volume, and high-throughput compared to our autoclave. Investigating adoption in a variety of facility demographics accelerated the design process as we narrowed our scope while gaining a better understanding of how our target users fit into the larger healthcare system and procurement chain.

The product also helped engage other stakeholders, such as buyers and manufacturers, as the level of execution conveyed a significant commitment and competence on the part of the design team. The team was able to interview buyers, manufacturers, and distributors for the government sector supply RHPs and rural hospitals. A thorough understanding of the procurement chain (from multiple angles) and the market player's individual incentives allowed us to better tailor the autoclave to their needs as well. Many university student teams approach these domestic gatekeepers with their next great development product or service, but almost always fail to deliver due to lapses in commitment or inability to execute their plans. Our product, although a prototype, was reasonably polished and allowed us to enter serious conversations and partnerships with the aforementioned stakeholders.

Ideally collaborative stakeholder partnerships would be forged from the beginning of the project, especially with a manufacturer. The availability of cultural and business information would increase market viability, quality of design for manufacture, domestic networking potential, and overall credibility with local partners. To allow researchers to focus on the academic facets of project development while simultaneously ensuring that products are still advancing down the path to market, manufacturing partners are key allies that should be pursued at the beginning of the project. However, such relationships are very difficult to establish with early-stage student projects as students typically lack the sustained commitment over time that is required for successful product development.

Fast and iterative design fueled by this field research was critical to our process of not only product design but also the market analysis and interfacing with stakeholders. At early stages there is typically a lack of information about target users and market analysis. Given these limitations, we suggest an approach of developing a functional prototype suitable for long-term use that can be tested by local partners in the field. This provides the researchers with valuable information relevant to continued use that is not apparent from cursory interviews and co-design exercises, and is fundamental to sustained behavioral change.

6.2 SUPPLY AND DEMAND STRUCTURE

A concise business case is also important to develop very early on in order to understand the product's potential for commercial success. The general supply-demand relationship (who is selling to whom) is either business to consumer (B2C) or business to business (B2B) and is a very important initial distinction. Autoclave sales qualify as B2B transactions since the manufacturer will sell to governments and other large enterprise buyers. B2B structures heavily

emphasize the role of the buyer as they are truly a gatekeeper to product adoption. B2C transactions decentralize the purchasing decision, but emphasize the importance of widespread product awareness in the target market. This typically necessitates a focus on advertising or other forms of marketing including word of mouth. We found that word of mouth is by far the strongest advertising in Nepal.

The second critical business consideration is the choice between local or central manufacturing. Local manufacturing and sales concentrate expertise to a small geography and make downstream problems like maintenance and repair trivial as the required expertise and tools are already available locally. This manufacturing paradigm also allows for significant local product evolution to fit the local market as the manufacturer and users are in close proximity and communicate regularly. Unfortunately, this local manufacturing often has trouble scaling as replicating the “pod” of expertise and equipment is difficult and no domestic stakeholder is incentivized to replicate the pod or scale. The learning curve is usually steep for not only manufacturing, but also from user training and financial limitations.

Central manufacturing dramatically improves the build quality, robustness, quality control, manufacturing capability selection. High levels of quality control are especially critical for healthcare products like the autoclave, where quality can be the difference between life and death. On the down side, Geographical separation limits communication between users and the manufacturer, slows product evolution, and make major repairs complex. Central manufacturing also introduces a new set of stakeholders whose commitments are all vital to success. These stakeholders include the distributor and buyers.

6.3 DESIGN WITH INCOMPLETE INFORMATION

The ability to design without a semi-complete understanding of the problem is common place when stakeholders are very hard to reach but the general problem is obvious enough and important enough to pursue despite a lack of information. While partnering with committed local partners is obviously preferred, unavailability of local partners necessitates some guesswork. The design assumptions should be explicitly stated early on in the design process and tested individually. A shortcoming of the autoclave research was the failure to quantitatively evaluate each assumption in order to accept or reject the assumption. Nonetheless, some of these assumptions were inherently hard to quantify, especially the relative importance of various softer design features (e.g. aesthetics, build quality) and market forces.

For those aspects that can be measured, surveys are a vital tool. Surveys for the developing world are commonplace but continue to suffer from significant reporting bias despite good question framing and careful execution of the survey. Question framing helps avoid “leading” questions that predispose survey takers towards a specific answer.

However, our team found that the survey environment has a profound yet nuanced effect on responses. As was discussed before, the presence of a superior causes subordinates to defer to the superior and never contradict his responses. Superiors are also overeager to converse in lofty language as a sign of social status, even though these superiors probably had the least experience interacting with the autoclave itself. Presence of a foreigner and appearance of a donation predisposes local partners to give overly needy accounts to emphasize the importance of the problem you are trying to solve and overly positive design reviews in the hope of receiving the next device. These subtle factors were only understood through translation from the Nepali students on the team.

Ideally, only local questioners will ask the questions to isolated individuals to get the most accurate understanding of clinic needs. In order to test this hypothesis, we sent a local Nepali student out to visit over 60 health posts around Nepal to ask what staff needed most without the presence of any donated goods or foreigners. He found that health post staff desired training on basic medical techniques over equipment or consumables, something they never brought up during the autoclave deliveries or follow-up surveys. These findings show that subtle reporting bias can significantly distort a researcher's understanding of the local environment and that rural health post staff find personal development very important as it elevates their social standing and their ability to treat patients.

For further resources, researchers should consult anthropologists and a variety of publications listed below:

- Thomas, Alan and Mohan, Giles. *Research Skills for Policy and Development: How to Find Out Fast*. Sage Publications Ltd. 2007
- Banerjee, AV, Duflo, E. *Poor Economics: A radical rethinking of the way to fight global poverty* Public Affair Books
- JPAL - <http://www.povertyactionlab.org/>

6.4 COMPETITIONS AND NETWORKING

While development work does have academic dimensions, most work is fundamentally applied and requires many skills that are not formally developed in the classroom. I found throughout the project that the ability to concisely pitch your idea to funders in the US requires developing a preliminary business case for the technology and understanding the technology's value proposition. In the case of the autoclave, and many other developing world projects, a thorough understanding of the business setting is a primary driver of initial design decisions. While some researchers are able to partner with organizations that have these skills, many overlook these gaps in their pitch and suffer for it.

The entrance in competitions significantly accelerated my pitching skills as well as formation of a team. Competitions, such as the MIT IDEAS competition, gave me a rallying point to attract new members, a good structure and direction for work, and hard deadlines to work towards. The competitions also point out very early where the idea lacks substance. Competitions were a valuable networking tool for our team, facilitating access to a wide variety of support networks and other advisors with an eclectic mix of perspectives. However, the standard warnings associated with networking still apply: the yield of useful contacts is usually very low and free advice should always be taken with a grain of salt. The best way to maximize the efficiency of network exchanges is to understand where the person is an expert and focus questions on that area.

In an attempt to help future development teams sort through the maze of opportunities at MIT and beyond, our team recommends the following competitions and contacts:

MIT-based resources (Grants)

- MIT IDEAS Global Challenge - <http://globalchallenge.mit.edu/>
- MIT Public Service Center (PSC) - <http://web.mit.edu/mitpsc>
- MIT International Development Initiative (IDI) - <http://web.mit.edu/idi/index.htm>
- MIT Carroll L. Wilson Fellowship - <http://entrepreneurship.mit.edu/clw-award>
- Enterprise Africa Business Competition
- MIT 100K - <http://mit100k.org/>
- MIT founder skills accelerator - <http://entrepreneurship.mit.edu/fsa>

External Resources (Grants)

- Startup Chile - <http://www.startupchile.org/>
- ASME iShow - <http://www.asme.org/events/competitions/asme-ishow>
- TiE accelerator - <http://www.greenhornconnect.com/news/tie-challenge-new-startup-accelerator-quickly-turn-great-ideas-real-companies>
- NCIIA eteam grant - <http://nciia.org/grants/eteam>
- NCIIA Sustainable Vision Grant - <http://nciia.org/grants/sustainablevision>
- Echoing Green - <http://www.echoinggreen.org/>
- Ashoka - <http://www.ashoka.org/>

Mentorship Opportunities

- MIT Venture Mentor Service - <http://web.mit.edu/vms/>
- Kopernik - <http://kopernik.info/>

6.5 TEAM BUILDING

The team for any development project should have committed partners with a significant cultural understanding and language proficiency. These are skills crucial to early design stages and more importantly execution in the field. A combination of these skills and commitment to the project can be found either at a domestic organization in country (NGOs, iNGOs, or small for profits), but these groups usually have a low level of commitment to your particular project as their priorities take precedence. Alternatively, there is a wealth of MIT students, probably from the countries where the intervention is being piloted. These students typically have the cultural understanding and may or may not be from rural or poor areas. For those who are from better off families, they will likely have connections with domestic players with power to enact change, if properly motivated. Alternatively, students from less affluent areas most likely went to a charter school, and many of their classmates have stayed in country for further schooling and their family and friends network can also be used to find local partners. These students have very valuable unique insight into the country as they have lived through poverty as well as the affluence of the US.

The autoclave team was lucky enough to interact with two Nepali students at MIT who were interested in development work. They were integrated into the team very early, during the initial design of the first prototypes. The Nepali perspective was critical to gain a picture, albeit fragmented, of the healthcare system and general cultural context.

The domestic team should be well-rounded beyond the local understanding to include experts in business, engineering, and communications. The importance of varied skill sets should not be understated. The ability to network your way into groups with these skills is critical, especially when no partnering organizations have these skills.

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8 APPENDIX A – STERILIZATION METHODS

Sterilization – Categories^{1,2}

Antigens: Bacteria/Fungi, Viruses, Spores, Prions

Options (DPs)	Advantages	Challenges	Review
Heat	<ul style="list-style-type: none"> • Versatile • Penetrating (Can sterilize wrapped instruments) 	<ul style="list-style-type: none"> • Typically energy intensive • Requires heat-stable substrate 	<ul style="list-style-type: none"> • Speed: medium • Danger: low
Chemical	<ul style="list-style-type: none"> • Can be very fast • Sterilizes plastics and other heat-unstable things (<60C) • Little to no electricity required • Doesn't require heat-stable material (plastics) 	<ul style="list-style-type: none"> • Requires relatively exotic compounds • Consumable • Some can rust instrument (oxidative compounds) • Hazardous 	<ul style="list-style-type: none"> • Speed: slow-fast • Danger: high (often toxic/carcinogenic)
Radiation	<ul style="list-style-type: none"> • Energetically efficient • Varying form factors, some very small/scalable • Zero material consumable 	<ul style="list-style-type: none"> • Electricity required • Hazardous 	

¹http://en.wikipedia.org/wiki/Sterilization_%28microbiology%29

²http://www.google.com/url?sa=t&source=web&cd=5&ved=0CDQQFjAE&url=http%3A%2F%2Fwww.reproline.jhu.edu%2Fenglish%2F4morerh%2F4ip%2FIP_manual%2F11_Sterilization.pdf&rct=j&q=how%20long%20does%20it%20take%20to%20sterilize%20with%20uv&ei=W_SaTNm3KYG88gbkwvyHAg&usq=AFQjCNEuIFm8DRVJ_wPGHSDO20y7VbrT1Q&cad=rja

Heat Sterilization

Antigens: Bacteria/Fungi, Viruses, Spores, Prions

Options (DPs)	Background	Research/Analysis	Notes
Heat – Steam	<p>Most common sterilization method</p> <p>Validated with</p> <ul style="list-style-type: none"> • heat tape • spore viles 	<p><u>Specs</u></p> <ul style="list-style-type: none"> • 121 °C 15-30min (2atm) • 134 °C 3-5min, (3atm) <p>~260kJ/100mL to heat 25C water to 121C steam @ 2atm ~266KJ/100mL to heat from 25C water to 134C steam @ 3atm ~5/6 of energy goes into phase change</p>	<ul style="list-style-type: none"> • Fast • Very versatile • Requires heat stable substrate • Eliminates everything but prions • Prions can be reduced by 2.5log in 134C for 18min
Heat - Dry	<p>can be used on powders and other heat-stable items that are adversely affected by steam (no rusting of steel)</p>	<p><u>Specs</u></p> <p>160 °C 2hrs 190 °C 6min unwrapped, 12min wrapped</p>	<ul style="list-style-type: none"> • Slow (forced convection can make faster) • High temps required • Requires heat stable substrate
Flaming/incineration	<p>Flaming used for small metal and glass objects</p> <p>Ethanol flaming used for glass “hockey stick” spreader</p> <p>Incineration for sterilization of medical waste before disposal</p>	<ul style="list-style-type: none"> • Destructive • Leaves ash residue 	<p>Infectious material can be “sprayed” onto surrounding objects during initial heating</p>
Boiling Tindalization- (cycles of boiling)		<ul style="list-style-type: none"> • Kills vegetative bacteria + inactivated viruses • Cycling (Tindalization) kills heat resistant spores because heat activation induces germination which makes the spores heat sensitive 	
Glass Beads		<p>Used in Dental offices</p> <p>Not supported by CDC or FDA</p>	

Chemical Sterilization³

Options (DPs)	Research/Analysis	Notes (Research, Risk, Counter-measure)
Ethylene oxide(EtO)	gas is commonly used to sterilize objects sensitive to temperatures greater than 60 °C and / or radiation such as plastics, optics and electrics. Ethylene oxide treatment is generally carried out between 30 °C and 60 °C with relative humidity above 30% and a gas concentration between 200 and 800 mg/l, and typically lasts for at least three hours.	<ul style="list-style-type: none"> • Treats temperature sensitive materials • Slow – 3 hrs • Flammable, toxic, carcinogenic
Ozone	<ul style="list-style-type: none"> • Very strong oxidizing agent – oxidizes most organic matter (pharmaceuticals, organisms, etc.) • Used to sterilize water, air, and some surfaces • Can be produced from arcing over air, produces nitric acid NHO_3 • Kills prions 	<ul style="list-style-type: none"> • Rusts metals really quickly • Very toxic and unstable, must be produced on site
Bleach	<ul style="list-style-type: none"> • Bleach kills many organisms on contact, but for full sterilization it should be allowed to react for 20 minutes. • Bleach will kill many, but not all spores. 	<ul style="list-style-type: none"> • Highly corrosive. • Bleach decomposes over time when exposed to air, so fresh solutions should be made daily.
Hydrogen Peroxide (Dry Sterilization Process) AKA gas plasma sterilizaation	<ul style="list-style-type: none"> • http://en.wikipedia.org/wiki/Dry_sterilization_process • H_2O_2 @ 30-35% under low pressure conditions • bacterial reduction of 10^{-6}...10^{-8} • Originally designed for the sterilization of plastic bottles in the beverage industry, because of the high germ reduction and the slight temperature increase • Suitable for medical/pharmaceutical applications 	<p>Process:</p> <ul style="list-style-type: none"> • Evacuate + introduce H_2O_2 (vaporize @ low pressure) • • Does not penetrate well, doesn't work on linen/paper
Peracetic Acid, Silver		Relatively rare materials

³[http://en.wikipedia.org/wiki/Sterilization %28microbiology%29](http://en.wikipedia.org/wiki/Sterilization_%28microbiology%29) - Cleaning methods that do not achieve sterilization

Radiation Sterilization⁴

Options (DPs)	Research/Analysis	Notes (Research, Risk, Counter-measure)
Gamma Rays	<ul style="list-style-type: none"> • Very penetrating • Commonly used for disposable equipment • Requires bulky shielding for operator safety • Storage of radioisotopes (usually Cobalt-60) • Never turns “off”, so always hazardous 	<p>Fast Eliminates everything but prions</p>
Electron processing beam	<ul style="list-style-type: none"> • Similar to gamma rays • “On-off” technology • Higher dose rate, lower exposure time (reduced chance of polymer degradation) • Less penetrating than gamma rays 	
X-rays	<p>X-ray penetration is sufficient to treat multiple pallet loads of low-density packages with very good dose uniformity ratios. X-ray sterilization is an electricity based process not requiring chemical nor radio-active material</p>	
UV	<ul style="list-style-type: none"> • Disrupts DNA base pairing causing thymine-thymine dimers (T-T) • Can be used to produce ozone for water sterilization • UV irradiation is routinely used to sterilize the interiors of <u>biological safety cabinets</u> between uses, but is ineffective in shaded areas, including areas under dirt (which may become polymerized after prolonged irradiation, so that it is very difficult to remove). It also damages some plastics, such as <u>polystyrene</u> foam if exposed for prolonged periods of time. <p>http://en.wikipedia.org/wiki/Germicidal_lamp http://en.wikipedia.org/wiki/Ozone#Ultraviolet_light</p>	<ul style="list-style-type: none"> • Cheap 10-30USD, 100+ for entire system • Small • Requires electricity • Some danger <ul style="list-style-type: none"> ○ Damage to retina+cornea ○ Sunburn • Only sterilizes surfaces that UV directly hits and potentially water if production of ozone occurs

⁴http://en.wikipedia.org/wiki/Sterilization_%28microbiology%29